have presented these topics over time and I have added new material to it. I think it's been clear to the panelists that some of the literature claims that there are excellent results by location, favorable in other areas, and questionable or poor. Some of the data are assuming that there are no differences. You saw two beautiful presentations right before me where their studies are not showing these type of situations. So perhaps bone density might be a critical factor rather than exact location of the mouth.

We must also consider dimensions of implants as they relate to the different shapes of the teeth in the different parts of the mouth, as it may become a problem. This happens to be a cylindrical coated system done in a total edentulous mandible with the ad modem Branemark method of four, five, or six implants in the synthesis with a cantilevered design, bilateral, cross-arch support.

These cases are totally different than partial edentulous unilateral types of cases that we're predictably doing in our practices today with sinus augmentation materials and the partial edentulous non-splinted, cross-arch results. So as clinicians, we are seeing excellent results in these more complex cases as well as the more straightforward mandibular cases.

The density of bone, I believe, is a clinical parameter which is much more important than concepts such as diameter and length, and I believe that the literature has been presented at this meeting that we have seen greater failure in the porous type of bone which tends to be in posterior areas, but not always.

Patient expectations are a clinical concern. We have a dentate skeleton here versus a severely atrophic situation. With a super-imposed tooth, we can see the clinical demand that is put on the practitioners both in the surgical and prosthetic arena to replace the missing parts of tooth structure, soft and hard tissues, and the cases are dramatically different.

We have this caricature from colleagues of one of the implant systems. We must talk to our patients and find out what their requirements are. This particular patient came to me, was unhappy with their situation. Cosmetically, they were unhappy with it. It did have hygiene access. You do see some soft tissue resorption and you do see some radiographic resorption from this cross-arch case. I would agree with them that they are having some complication. Although these implants are not failed, they are in a compromised state.

This particular patient was in an automobile

accident several years before I saw the patient. You can see some residual scarring. This was done approximately seven or eight years ago by myself. I did not do techniques of isolated bone augmentation as I would today, but we were able to enhance the zone of gingiva, place two successful implants. Here, you can see, is a preangulated component. Now, we can definitely get better aesthetics today. This is the patient's smile, so she is not particularly offended by that, but smile concerns and aesthetic concerns are important, so we must consider the patient expectation.

What are the medical and surgical risks? I believe that endosseous implants are a rather straightforward discipline for surgical therapy and we have the same risk factors as any other oral surgical type of procedure. There are some medical considerations. Uncontrolled diabetics, some of the animal studies are now coming out. Mark Nevans, Ron Nevans' son, has done a very nice study on diabetes. There's work on osteoporosis where it may or may not be a problem. There's definitely some information that age is not particularly a problem, but the information on smoking is that it clearly is a problem.

This particular case I had done about four years before she had represented with this lesion in that particular area. Now, the implants looked to be reasonably

sound radiographically. We disassembled the frame and we saw this particular type of lesion. Now, in my aging population in Florida, I was not adverse to think about squamous cell carcinoma as a particular diagnosis for this particular case since she was a smoker and radiographically did not show any clinical signs of breakdown. And it did turn out that that was, indeed, the clinical diagnosis of her particular case.

As we further developed this etiology slide, we now have two major categories, biomechanics and microbiology. So we've left the patient factors and now we're into certain other aspects. So with etiology, we can look at infectious processes or traumatic or overload factors, or, as we see oftentimes in the dentition, them working together as cofactorial, and then, of course, patients may have some systemic input.

What causes crestal bone loss? We rarely see periapical lesions around implants. We see them breaking down at the crest. If we look at this list of reasons, many of them are operator involved. There are a few implant design which may be from the manufacturer's perspective, but many of these are controllable by the clinician as we are diagnosing and handling the case treatment.

These are two signal tooth molar implants that I

placed approximately eight years ago, prior to the advent and the popularization of wide-diameter implants. Both of these have some crestal bone loss. They're both still functioning and successful implants. But I think we can do much better for our patients with a wider design in this particular type of clinical indication.

How about two standard size implants rather than one large-diameter implant? I'm sure the manufacturers from a marketing perspective would prefer this treatment plan because they can sell two implants rather than one. Well, we now have a manageable metal fircation which is reasonable to manage. Here is an indication where the implants were closer together and this is actually a non-manageable fircation type of a situation which may break down over time. So the data is now coming in on single-tooth sites and molar areas with a single wide implant or multiple implants.

As you can see on the upper case, implants are being placed predictably into the teragoid area so we don't have to do sinus graft. So as a clinician that's doing a variety of techniques, we are attempting to utilize a variety of methods, both teragoid implants, sinus graft, as I showed earlier, implants below the sinus, and then a total edentulous mandible can predictably, with a cross-arch

design, give us a cantilevering effect.

What about a unilateral cantilevering effect, and you see over time, this implant and the prosthetic coping has separated from the joint and this whole prosthesis had to be redone with a broken abutment screw on top of the implant.

This is a more dramatic problem related to cantilever. These are two small-diameter microvent-type implants and you see the excessive cantilever that was exerted onto this single implant, two teeth on a 3.25 diameter implant, another dramatic example of an explant of a microvent 3.25 diameter with two teeth for one implant.

Here is a short titanium screw implant, again, in an overloaded situation where you would have a short implant supporting its tooth and an adjacent pontic [ph.] attached to a natural tooth with an attachment mechanism. This is something we find if we carefully review our x-rays. You can see a little bit of crestal loss, but what's interesting about this particular case is the natural tooth splinted to this implant prosthesis had a coping device cemented on the tooth and we see a separation area right here. So we're getting what appears to be an intrusion of the natural teeth. So when we're adding teeth to implants, we sometimes have this intrusion that has taken place and several

colleagues are investigating the etiologies.

If I could get ten or 13 millimeter long implants in a unilateral design, I would feel comfortable with a cantilever situation for most patients. I would much prefer not to have a cantilever as you see on the x-ray on the right slide.

In a cartoon manner, these show graphically what we are faced with as clinicians with regard to crown implant ratios. If you have a short implant and you're restoring a tremendous amount of former bone and clinical crown, a very simple force can cause what some people like to call overload or a traumatic force. On the other hand, if you have a well-formed ridge, a well-anchored implant, it takes a much dramatic greater force to actually give an overload situation to that design. So while each force might be similar, it could be greater in a site where the implants are shorter in dimension. So as a clinical recommendation, I think the FDA's consideration of length of implants should be within the guidelines that you presently have.

There was an interesting paper from the colleagues about smaller diameter. That may be something that you may want to look at for certain types of indications. Where I could get in four implants, one for each tooth, I believe that's a very predictable situation.

Splinting implants to teeth is not desirable. When done properly, it can work. However, if you look through the literature, Professor Rangert, he has actually talked about "a little bit of play" in the fit over the hex, which helped the situation get a teeter-totter effect, where you're tying a rigid implant to a tooth with a periodontal ligament. I'm not sure that's exactly what we would like to see, but he had mentioned that in his lectures.

The ITI group are much more confident in their concepts of splinting to natural teeth and they actually would recommend a permanent cement. So you see a diversity in what's recommended to the clinicians. I would prefer to do it not with teeth. I'd rather do it just implant-supported.

I've shown this case because it shows beautiful technical laboratory work, probably as lovely as most that you've seen in any of today's presentations. This case was treatment planned to have the natural dentition by itself and the implant restoration by itself. However, when I saw the patient back, what do I see over here? We see a very significant misfit of the case and it is very sad for me as the surgical member of this team to tell my highly qualified restorative colleague and his technician that they basically have to strip this case and do it all over again or you're

setting this case up for a mechanical problem.

We have looked at breakdown analysis with a lot of factors and prosthetic design comes into play. This is one of the cases that was done by my restorative colleagues in the past. You don't have to be an orthodontist to see that that's a poor prosthetic design. So this is what is contributing to implant complication.

Here is another case with cylindrical implants with a large cantilever and these implants eventually failed and it was also attached to the natural tooth. So this particular prosthetic design was attached to a natural tooth. It had cementation on the natural tooth, a screw design over the implants, a cantilever in a unilateral manner, but I was proud that I enhanced the zone of gingiva, although we wound up losing the implants nevertheless.

Off-angle presentations--I believe that the clinicians today are doing a better job because we have augmentation, grafting, and regeneration to do prior to implantation or in addition to implantation. So I believe that the use of these preangulated components is less than it has been because we, as clinicians, are doing them in a much more precise manner.

This model, I got from one of my local laboratory technicians who asked me what type of components would I

recommend for these restorations. This is probably not acceptable therapy from a medical-legal perspective in today's environment with what we can do as clinicians in building up and augmenting ridges.

Component fit, I think, is critical, and that comes in the biomechanical arena. A single tooth restoration was placed and at low power, it looks not too bad. Clinical view, we did a new crown here, new restoration of the implant. Everything is looking good. But if you look real carefully right here and right here, there are slight gaps in the prosthesis. This one particularly bothers me because that's a cement zone, cemented crown, and I believe that these types of wiggling and jiggling could cause problems to the ultimate integration of the implant. So this, I would deem in my practice as an at-risk site and we would want this patient to come back at at least a three-month interval for recall.

This is an implant that I had placed in a patient at the time of surgery and I tapped it off access. Implants come in different types of material. This particular system, I believe, was a grade three metal and that is the yield strength numbers. Several of the companies have presented different types of titanium in their systems and they definitely have different types of yield strength. I'm

not sure that there's any improvement one way or another with integration rates, but there's certainly definite mechanical differences in the different types of materials.

This case had the cantilevering effect, because we did not have wide-diameter implants at that time. This is what it appears like radiographically, and when you first look at the x-ray, you don't really see much of what's going on. The patient presented with tenderness, probing, and a swelling in that area. I started disassembling the case and you see the difference between this site and this site is that this has the external hexagon from the top of the implant, whereas this one does not, and there it is.

And at SEM analysis, you see that the abutment screw acted as a fulcrum, and if we go back just to look at the x-ray for a second, when there is bone loss, for whatever the reasons of crestal bone loss, and there were several reasons presented, these mechanical forces of the abutment screw can act as a fulcrum to have fatigue of the implant metal and it could fracture.

Another cantilever design of a fractured implant. This happens to be a fractured cylindrical titanium alloy implant, whereas that's a CP titanium implant.

I believe Dr. Moreland's practice, he claimed that he had not seen in his practice any abutment failure that

led to implant failure. I'm not sure that's exactly what happened in this case, but this is an abutment failure and the distal implant had become loose from teeter-totter, or maybe it was a coated implant design and had inherent concerns, but I believe it was more of a mechanical consideration.

This particular prosthesis, you can see, has no porcelain in this area. This particular patient had a tremendous and powerful bite. They broke the abutment at this point here and we tapped the case out. We were able to remove the different components, because it was a screw designed case. We placed a healing abutment, referred it back to our restorative colleague, and the case is now able to be redone prosthetically.

Now, this case is interesting because it underscores what happens to our patients if they have a complication or a failure. This is something that's not dramatic. It is able to be redone and replaced, and here are the pieces being broken apart.

This advent of a torque driver has been very helpful to us as clinicians because we're now able to induce the screw tightening to the manufacturer's specifications, which we weren't able to do in the past.

This retrieval study by Andy Bucks on a Sterios

HA-coated screw shows a couple of things, good HA integrity on the surface and excellent integration with a single tooth in load.

A more dramatic explant from the work of Joel Roselick, this implant was also an HA-coated screw in a maxillary sinus augmentation case, and you see intact HA in load. The implant had fractured. You still see some of the osteograph end particles still reabsorbing over time, but you see in function in a compromised bone site the HA material can remain intact.

This was an interesting case clinically because I had had three implants. We had good zones of gingiva and we were seeing this radiographic evidence of breakdown. Prior to opening up the case, I had done some culturing and DNA probe analysis and did not get any positive results to any of the pathogenic flora. We opened up the case and I did not see the pitted HA surfaces we sometimes see when we have problematic infectious sites on the HA-coated implants.

Clinically, there were steep cusps prior to this occlusal grinding that I had performed and we had deemed this case to be more of an occlusal-related problem, and this is that same patient eight years later with no evidence of further breakdown and the patient judiciously uses clohexadine rinse and we have flattened out the occlusal

scheme in that particular case.

HA definitely has positive and negative effects. This implant case was a three-unit bridge. We see some breakdown. This tissue was biopsied after I had performed the clean-out and I asked the histopathologist, is there any refractile HA material in this granulation mass, and this area right here, all these dark purple areas, are actually particles of hydroxylapatite. Now, if we go back to the clinical design, we see a three-unit bridge on a tooth, and would I do this case the same today? No. I would have a single crown and I would have three implants splinted together. So is this an HA coating problem or is this a Jack Krauser problem?

I was interested in peri-implant infection, and this is just one representative sample from a study that I had done at Ohio State University, one of the graduate periodontists, and we looked at induced peri-implantitis on titanium plasma, HA, and titanium surfaces of exact geometric design screw implants and this was a phagocytotic response to some of the HA that had come off that particular site. We did not see that type of phagocytotic response with the titanium or the titanium plasma. So when Dr. Lore Langer mentioned that implants failed differently, I would concur.

This is what an HA implant looks like when it's in an infectious failing situation. You see the pitted situation on the surface of the implant and you see some bone loss in this area. Today, with augmentation materials, we're able to take this out with a trephine, rebuild the ridge, and redo the case. However, pre-clinically, we have better treatment planning methods and we probably would not run into this because we would not be involved in overloaded situations.

Lore Langer presented a paper that I had done with Thomas Golick that was published in 1991 on consecutively placed HA-coated implants. My contribution was approximately 1,200 implants and Tom Golick's was over 2,000 implants. The study was called a long-term study, but if you really look at the data, it was like some of the other studies where the cases were from one year to seven years.

So taking that criticism properly, I reanalyzed the same data and took only implants that were restored for at least five years and we retrospectively analyzed that information and I did that with a colleague from Sulzer-Calcitek and I did receive a commercial stipend for helping with this project. This data was then presented to the American Dental Association for integral systems ADA provisional and final acceptance as an approved device from

ADA.

So when we looked at the 1,200 originally that were less than the five years, there were actually 325 that were at least five years or more in function. Any failure that had occurred prior to that was included in the failure situation.

Now, if you looked at the results, my area of failure tended to be in the posterior regions greater than the anterior regions, and that tended to be similar to data that was presented by Axel Kirsch at that time, in the early and middle 1990s. He and I would present these data with those types of results. This implant survival by location chart shows really no difference between maxilla and mandible, and in the overall success rate, we had that situation for both arches.

Now, my x-rays were sent to an unknown site and the reviewer was unknown to me at that time, hence the double-blindness, and we had an independent review of the x-rays and it turned out that Marjorie Jeffcoat at Alabama-Birmingham did the analysis of my one to five or greater years post-operative x-rays to determine the bone loss analysis based on, because of her computer program, she could only get a mesial and distal change. Breaking out, because it says all centers, just my data, Krauser's data,

it shows between 0.2 and a little more than one millimeter of the study that she had seen and it was a progressive situation and it is an average. I think Dr. Heffez asked the previous speaker about how do you determine the bone loss. It's a mean situation of the bone loss. So we did not see tremendous breakdown situations.

These two cases are over 12 years old. They were done in 1985 and these were recalled in '97. You see from the original protocol design, these implants can work nicely in both mandibular and maxillary cases.

I also want to share with you the poor prosthetic concept that was incorporated in both of these cases because the components as given by the manufacturer in 1984 were hardly as good as what we see today.

I just have about three more minutes?

DR. GENCO: About two minutes.

DR. KRAUSER: I'll try to wrap it up. Mambelli was the first to talk about peri-implantitis and microbiological effects and he presented the site-specific nature of breakdown. I believe it goes hand in hand with peri-implantitis or concepts of biologic width when we as clinicians are working with adjacent teeth. So we can handle crown lengthening and sinus augmentation at the same time, and this is a more contemporary way of handling our

implantations. So we're able to get a better fitting restoration and a better fitting implant restoration with a sinus graft as an isolated area.

I'm doing a small pilot project with Dave Cochran where we're intentionally placing one-stage implants slightly above the crest and we're following them to see if having the microgap above the bone crest makes any difference and we're following a few cases. We have seen microbiological breakdown plaque on these titanium screw implants on titanium as well as HA-coated implants. We believe that the design of implants are risk factors from a microbiological perspective. We talked about roughness earlier today, the hollow and the solid designs, one-stage versus two-stage designs.

This is an interesting case because somebody brought up galvanism. This was a subperiosteal implant in the posterior with root form implants in the anterior and a superstructure of a totally different material and you could see the soft tissue complication and you could assume what the underlying bone complications are.

Those are just showing some problems of patient hygiene. This shows the site specific nature of breakdown. Here, prosthetic design and implant placement became a problem with framework, as it did with this one.

Another situation with a prosthesis over the implant is causing a problem. Sometimes the misfit of the components can cause a fisula, and when it gets severe, you will get an explant device.

Surgical protocol is interesting. Tarnow and Sharf has presented a paper where dental operatory with an aseptic protocol yielded results as good as operating room procedures.

So in summary, there's a great list of biomechanical and force-related factors that go into implant complication and failure. So in conclusion, we, as clinicians, will have patients that are good, the bad, and the ugly, and my final etiology of implant loss slide has added to it the iatrogenic factor, because I believe as a clinician, we are the ones that are causing the complication, not the manufacturers.

So I would like to state that a reclassification for class II will be just fine for a clinician's perspective and education, which we can get because the manufacturers will have more money to spend, would be acceptable.

Thank you for your time.

DR. GENCO: Thank you very much, Dr. Krauser.

We're running a little late. I think what we'll do, unless anybody has a burning question of Dr. Krauser,

we'll proceed on to Dr. Sendak. I'd like to say that what we're going to do is we're not going to take a break this afternoon. So if any of you have to get up and leave for a minute or two, we'll understand.

DR. SENDAK: Thank you, Dr. Genco. I appreciate coming at the tail end here. I know there's a lot of pressure on time. I'm going to try to be very responsive to that issue and keep my presentation to an absolute minimum.

I had the opportunity before to present on mini-dental implants as temporary or transitional devices. I am the inventory of the Sendak's mini-dental implant. I'm also here as the person involved with regulatory matters, and so I think I'm in a good position to offer some additional commentary that I was not able to present last time at the November meeting. These issues really relate to just a few areas that, interestingly enough, were covered in some respects by quite a few of the other presenters today.

One of the most obvious ones that comes to mind is that, as you know, the mini-dental implant is devised or is conceived as a transitional or temporary implant. It addresses perhaps the most vexing problem facing skilled implant specialists as well as entry-level practitioners and that's the mutual need to smoothly manage awkward transitions from dentate to partial or total edentulous

patient status without resorting to often emotionally devastating removable prostheses at just the wrong moment in the whole process, the reconstructive process.

Also, we have to think about the aging of our population today, the costs of implant dentistry, the time-consuming aspects of it. There are many issues that we are facing today that perhaps mini-implant strategies can begin to address. The temporary transitional use to avoid some of the things that Dr. Krauser was talking about in terms of iatrogenic problems. Dr. Deporter and others were referencing unknown factors in causing a lot of loss of implants for reasons that were somewhat obscure.

Some of these clearly could be suggested to occur because of iatrogenic overload of the devices, the implants, fixtures, while they're integrating because of simply iatrogenic overload from removable prosthodontics, and we're very quick to say how bad a removable prosthesis is, and this is causing all kinds of problems. And we're quick to say, or to suggest, at least, that these are devices that are really creating tremendous problems. They are creating problems, but what other alternatives do we have if we are not going to give a patient a removable to get them through these difficult transitional periods. So that is where, perhaps, the mini-implant has its most immediate and obvious

application.

The device itself is a self-tapping titanium threaded screw indicated for intrabony and intraradicular transitional applications to permit immediate splinting stability and ongoing fixation of new or existing crown and bridge installations of full or partial edentulism and employing minimally invasive surgical intervention. When I say minimally invasive, I mean it. You do not, in most of the applications for this device, have to incise tissue, flap tissue, and ultimately suture tissue, which sounds like pie-in-the-sky time, but, in fact, when applied properly, can be very readily utilized with that particular protocol, as we'll discuss very briefly here today.

While CP titanium may be utilized, the preferred titanium alloy, the titanium 6 aluminum or vanadium formulations are long accepted by a compatible metal, which Dr. Krauser again addressed a moment ago, which has the added benefit of significantly greater tensile strength than CP titanium according to ASTM specifications, the specification being B348, which demonstrates that there's a 62.3 percent greater strength, the tensile strength, than grade four CP titanium, which is the strongest of the commercially pure titaniums.

Now, also, a solid one-piece design for--remember,

this is a 1.8 millimeter width implant. It's certainly by far the narrowest implant that's come under discussion or observation today and, I'm sure, gives pause when you start to think about whether or not that's acceptable even for a temporary or transitional device.

However, we have been at this for over 20 years plus and we have found that once we made the switch from the CP titanium of the rather crude initial devices, which were essentially modifications of standard titanium root canal posts, manufactured at that time by Dentotis, once we made the switch to the alloy, the problem of fracture was eliminated, and I'll show very quickly just a few bits of data so that you can see, grasp what I'm trying to get at here.

As I said, the solid one-piece design for the combined screw and head portions provides added strength to offset the small diameter, the 1.8 millimeter width dimension of the MDI.

Total device lengths of 14, 17, 19, and 22 millimeters provide a sufficient range to encompass most available ridge heights encountered clinically, increasing the potential indications.

The ability also to deploy multiple MDI elements in the space typically occupied by a conventional width

fixture is an additional useful feature of 1.8 millimeter width MDIs that not only offsets the apparent reduced surface area in contact with bone but also increases the total number of abutment supports placeable for functional stress distribution in any given space.

The soft tissue effectiveness factors that relate to the health of the peri-implant soft tissue environment during the useful life of the mini-implant in situ is quite important, along with the commonly accepted signs of peri-implant health, which include lack of bleeding tendency, lack of pain and tenderness, lack of redness and inflammatory edema, lack of hypertrophic reactivity, and minimal pocket depth with a stable resumed hemidemosomal hypopolysaccharite attachment at the gingiva cuff level. There is also the still somewhat ambiguous issue of attached peritonized gingiva and its role in peri-implant soft tissue health.

Most contemporary opinion is perhaps best exemplified by the exhaustively documented American Academy of Periodontology view that while attached gingiva is not absolutely essential for peri-implant health, it is considered a useful bulwark against invasive pathogens and peri-implantitis.

The mini-implant occupies a unique position in

that its ultra-small 1.8 millimeter footprint permits it to be placed directly through small patches of keratinized gingiva, avoiding the areas of unattached tissue, which seem to heal at a slower rate, are associated with reactive edema, and ultimately seem to be less conducive to maintainable peri-implant health.

A retrospective assessment of the 575 mini-implants placed to date have clearly demonstrated the consistent peri-implant health surrounding these small devices and it is the considered opinion of our team that a significant component of this positive health factor may be attributed to the precise ability to target mini-implants into limited areas, keratinized gingiva, without the loss of significant soft tissue substance that often accompanies flap procedures.

Unquestionably, larger, conventionally-sized implants would blunderbuss such small attached tissue patches and end up at least partially in unattached gingiva, potentially, at least, compromising the perceived benefit.

The last issue I want to discuss is to how these are placed and why. They are self-tapping in the real complete sense of that world for a small device. There's an absolute minimal osteotomy or preparation. Minimal drilling is the essential distinguishing feature of all mini-implant

osteotomies. Fine-tapered diamond or carbide drills with copious sterile irrigation are the prime devices for initial penetration through crestal soft tissue and crestal cortical bone and then into the more cancellous medullary bone site.

This minimal osteotomy, usually comprising about one-third of the length of the typical 17, 19, or 22 millimeter length implant, is almost 80 percent of the time--80 percent of the time--sufficient to provide the initial bite for the take of the mini-implant into the bone, just, in effect, like a wood screw. That is truly a self-tapper, if ever there was one. Simple thumb wrench or ratchet wrench drivers are readily effective inserting devices, so then self-tap the mini-implant all the way to the level of the protruding abutment head portion of the implant.

Since the device is a one-piece machine system of unique simplicity, there's diminished potential for insertion complications, and as previously delineated, any misdirected starts may be readily corrected by restarting the insertion process in a different trajectory or contiguous location.

Occasionally, small stubborn areas of dense bone are encountered, not only in the synthesis region but with less frequency throughout the maxilla and mandible. In

these instances, an internally water-cooled 1.6 millimeter drill is used to lightly and briefly penetrate into these resistant strata but without greatly extending the process to avoid over-instrumenting the bone. Perhaps the most significant cautionary guideline in the entire MDI insertion protocol relates to avoidance of bony over-instrumentation. That's probably true about all implants, but certainly in this case, since there's virtually no real osteotomy going on here to speak of, this is critical in this case.

Osteo-integration can only occur on an immediate basis when maximal self-tapping by the implant is encouraged to happen without the usual fully realized osteotomy associated with conventional dental implant operations.

I would like to also say that we have addressed the issue of strength in a very specific way. We've asked the University of Alabama to do very carefully evaluated testing on yielding strength and on ultimate strength and we've basically shown that at 1.8 millimeters of width, we're getting, literally, with the mini-implants made out of the alloy, just about two times more effective ultimate strength and yielding strength than the CP titanium in this particular application. I am not suggesting that this applies outside of this milieu. This is a particular setting and particular application.

With this said, I have many other things I would like to address and talk about that I think you would find interesting and compelling, but I know the time is really very pressured right now.

So I'd just like to conclude by suggesting, with respect, that the FDA could perform a very useful function in leaving what is essentially or permitting what is essentially a very simple traditional implant device with considerable strength, one-piece casting ability, and easy insertion and reconstructive protocol to be placed into a class II category. I think it would then have its greatest application and usefulness in this field and we do need a device of this sort. After 22 years of applying it, I think I can speak with some satisfaction and assurance on this subject. Thank you.

DR. GENCO: Thank you, Dr. Sendak.

Are there any comments or questions from the panel?

DR. STEPHENS: Yes, I just have one.

DR. GENCO: Yes, Willie?

DR. STEPHENS: What would you consider the upper limits of the length of time that this implant ought to stay in, and is it different for multiple units than one unit, single units?

DR. SENDAK: Well, these, when they're placed, according to standards that we've just been suggesting, are free-standing and can support themselves. They are not sort of depending, they're not sort of leaning on anything else. They can be self-supporting and they get immediate integration. If you use the classic Branemark way of looking at it, you get a close--by self-tapping, you're getting an immediate integration. That should be self-tapping, or that should be integrated, rather, and that can be used in any one single application or multiple application. I've used them in all manner and variety of application.

I'm not sure I totally answered your question, though.

DR. STEPHENS: How long is temporary?

DR. SENDAK: Well, temporary, we like to use the term--I mean, for FDA purposes, we're using the term temporary strictly. I prefer the term transitional because one man's or woman's temporary is someone else's transitional, which could be for an extended period of time. It depends really on what the application is. What are you trying to do, in other words?

I think these can sustain themselves for as long--if they're placed according to the protocol, they can

sustain themselves for as long as necessary. They can be backed out easily when they're placed in for short-term periods because it's just a question of reversing the procedure. The 1.8 millimeter width permits a back-out without, even though they're a close approximation of bone, they're not integrated in the sense that a large implant cannot be really rotated back out. Yes?

DR. STEPHENS: Six months or five years?

DR. SENDAK: Well, as I say, I've had some inadvertently where patients--we've placed these in patients--my first case, about 23 years ago, was for a voice teacher who did not want to have any transition with removable. So we put a simple removable denture on top of a whole flock of these in the mandible where there was no room for anything except these, and I don't know whether I should be happy, apologize, or congratulate myself, but the patient is still wearing the same system.

Now, I am not standing here before the FDA and suggesting that that's the way anyone here should look at. But I think looked upon as a transitional device, I think it has enormous application in that respect.

Did I properly answer you?

DR. STEPHENS: Not really.

DR. SENDAK: Not really? Can I amplify on it?

How long have I had them in? Well, as I say, some have been in many, many years, sometimes because the patient wouldn't permit anything else.

DR. STEPHENS: We have to distinguish between temporary, or temporary but you can leave it for a long time.

DR. SENDAK: Well, temporary, if you're waiting simply for other implants to integrate, conventional implants, which is the sort of baseline application here. You have a series of implants. You don't want iatrogenic damage to those implants, classic implants, whatever type you choose to use. Any of those that were discussed today could be the kind of implant.

If you want to support a fixed temporary prosthesis or transitional prosthesis or whatever you want to call it during that period, these devices consistently have been shown to do that, and we received our 510K the end of last year, I'm pleased to say, because I think we were able to demonstrate that this, in fact, was the case. We also received--again, that doesn't perhaps have too much bearing on the whole situation, but we did receive a patent allowance for the whole device and reconstructive protocol, suggesting at least that this is an innovative approach to a classic problem.

DR. GENCO: Comments, questions, further?

[No response.]

DR. GENCO: Okay. Thank you very much, Dr. Sendak.

DR. SENDAK: Thank you.

OPEN COMMITTEE DISCUSSION AND VOTE

DR. GENCO: We will now proceed to the open committee discussion and vote. We have been presented with questions and considerations by the FDA and I'd like to have you look at those and let's discuss them.

The first is, as we know, all endosseous dental implants of all types are presently class II medical devices--class III medical devices. Given the information that we have received and heard regarding each subgroup of dental implants, do you think there's sufficient data to establish appropriate special controls to adequately control the level of risks and to provide a reasonable assurance that the device can be used effectively, and that really leads to the second question if class II is recommended.

Does anybody want to begin this discussion? Yes, Mark?

DR. PATTERS: Certainly for the root form implants, I would say there are very few things in dentistry that we have this much data and this much data which is

overwhelmingly positive in showing safety and effectiveness. So my answer for the root form implants would be unequivocally yes.

DR. GENCO: Okay. You're thinking, then, of class II recommendation with controls?

DR. PATTERS: I am, indeed.

DR. GENCO: Any further discussion of that for the root form? John?

DR. BRUNSKI: I was just going to ask just for a clarification, perhaps, from the FDA. I was reading through some of the documents on special controls and I understand that the use of a guidance document is a perfectly fine means of establishing a kind of a special control, and in that guidance document, a number of things can be often specified, correct? Am I correct in thinking that way?

DR. GENCO: Yes. What I've heard is, I think today and last November, we heard at least three types of special controls, one technical, standards for materials, standards for benchtop testing, standards for manufacturing, either GMP or ISO 901.

And then we heard another type of control, which was that as appropriate clinical investigation may be required, even though it's a 510K, it's a modified 510K, and please, people from FDA, correct me if I'm wrong on this, so

that those guidances with respect to the clinical protocols, number of studies, number of subjects, conditions of studies, outcome variables, et cetera, could be established, have been established, may be modified.

And then the third type that Dr. Marlin discussed and that is educational special controls. So I think those, if the decision was to reclassify it as class II, then those three types of special controls, any combination of which could be applied to these implants.

Okay. Let me ask, we heard root forms and I think we heard also about some unique root form implants. For example, we heard about the Sargon type. We heard and read about the teragoid implants. Now, when we mean root form, are we to include those two or the traditional screw, hollow screw, basket-type, solid core with one or another coating? I'd like to get you to think along those lines. What do we mean by--how are we going to define root form endosseous implants? What's included? Mark?

DR. PATTERS: I'd be willing to interpret that as broadly as possible. It will be the manufacturer's responsibility to show that their product is essentially equivalent. So I'd look at it broadly.

DR. GENCO: Okay. So let's go to the example of the teragoid. So what you're saying is that if the implant

was designed for the teragoid, if it's a root form type, that maybe the FDA might require clinical studies, as appropriate?

DR. PATTERS: Exactly.

DR. GENCO: Okay. How about the Sargon type? That is, you could interpret that as having a special retention device. Let's look at that in particular. Is that one with a retention device that's so unique as to remain in class III or what are your feelings? Would that be a class II, with in mind that one could require clinical studies, as necessary. Leslie?

DR. HEFFEZ: My impression of that implant, it's more--with an internal device, that it should be considered as a class II device and it would simply be a modification of an existing. That's my impression.

DR. GENCO: Okay. Are there any root forms that we've heard about today or read about since November that would not be in this definition of root forms? We saw pictures of those with fins, various types of designs. Any limitation in terms of diameter?

DR. HEFFEZ: My impression is that if the implant, the means of retention is primarily through the use of the screw-type device or cylindrical type device, that its principal means of retention is through that means an

alteration of its surface and it should be considered a root form implant. Any other modifications other than I've just--I mean, if the principal means of fixation is the cylindrical or the screw-type form, that it should be considered--

DR. GENCO: So you would include the bicortical screw, the Oratronics?

DR. HEFFEZ: Yes.

DR. GENCO: How about the last one that we heard, the Sendak mini-implant?

DR. HEFFEZ: The way I try and perceive this is that they should be almost grouped in the pattern of their failure. If they're going to fail in the sense that a majority of these fail and then simply remove the implant, it may be encased by fibrous connective tissue, I think that they should be lumped together. So I think the pattern of failure is the same and I would consider them all together.

DR. GENCO: Okay. Any further comments, then? I think what I'm hearing is that the mini-implants, the Sendak, the Oratronics, the Sargon, and the teragoid, plus the traditional screw, hollow--

DR. PATTERS: The bicortical screw.

DR. GENCO: The bicortical screw is the Oratronics. Yes?

MR. LARSON: Well, in the U.S., Oratronics refers to a blade implant. That's why Tronics Oral is--

DR. GENCO: Oh, Tronics Oral. So we can be very clear, Tronics Oral, the bicortical screw, the two-and-a-quarter diameter bite, the 26 and 36 millimeter length. Okay. John?

DR. BRUNSKI: And by the way, when you're saying teragoid, are you referring to the Onplant or the Zygomatic or--

DR. GENCO: No. No. Zygomatic is--

DR. BRUNSKI: Okay.

DR. GENCO: I purposely didn't bring in the Onplant. I mean, we could discuss that, but it doesn't seem that that is root form or is--not traditionally endosseous, although it could have an endosseous component. Now, if you want to include that, this is the time to do it. Jim?

DR. DRUMMOND: I guess I have a question as to a lot of these implants have much stronger clinical studies than other implants.

DR. GENCO: Okay.

DR. DRUMMOND: If we group them all together, do we then go back and ask for some of these newer products to substantiate or do we classify them as something else? I'm getting confused.

DR. GENCO: Sure. No, I think the special controls could include clinical studies, as appropriate. Now, the "as appropriate" is decided, I think, by the FDA staff. Tim, is that correct? In other words, we're dealing with five or six today, but you may get number seven tomorrow.

MR. ULATOWSKI: Right. You're dealing with what you have in hand--

DR. GENCO: Exactly.

MR. ULATOWSKI: --and if you're going to lump, you have to deal with the data in hand. Anything that comes down the pike, should you, for example, recommend class II, we'd deal with in a 510K with clinical data or whatever else you would suggest in determining, yes, it's in the same bin or it's not.

DR. GENCO: Right. So you could get the seventh next week with a new kind of fin or what have you, a little different, maybe significantly different, but still within the endosseous root form concept that you could make the judgment to ask for special--excuse me--special controls could include clinical studies.

MR. ULATOWSKI: Right, and also the class II and the 510K process allows for progression of technology over time as new designs come forward and data is assembled.

DR. GENCO: John, is that clear? In other words--

DR. BRUNSKI: Yes.

DR. GENCO: It may very well be that those that we've heard about today don't have sufficient data. I'm not saying they don't, but they may not. Excuse me, Jim, I guess you asked the question. I'm sorry. So that the FDA could ask for even some of those that we heard today for the data, even though they're class II, to approve the 510K. In other words, it would be a modified 510K with data. And then the other special controls are the technical aspects and education, if we think that's appropriate.

DR. BRUNSKI: Just the other clarification is, in November, we had that grid where we were also considering the indication at the same time. How is that figuring into the decision making?

DR. GENCO: Okay. One of the considerations that I heard then and heard today was the anatomic location. Is this what you're talking about?

DR. BRUNSKI: Well, also issues like for, let's say, immediate loading as opposed to delayed loading. You know, if a device is, let's say, class II or we decide it's a class II recommendation that something that's done in a delayed loading situation, we have to separately consider whether to specify something for immediately loading.

DR. GENCO: Susan, do you want to address that?

DR. RUNNER: From my review of the transcript last time, no one mentioned last time any special concerns about location, immediate loading, extraction sites, those types of issues. If you do have issues about them, you should let us know now. But the way I had interpreted from the last meeting, you just basically split it into those four groups, root form, blade, special retention, and temporary. You did not mention anything with coating or with any locations or other indications as being significant in terms of classification.

DR. GENCO: Do you feel differently now? Does anybody feel differently with respect to that particular question of indications, either anatomically, anatomic indication, or load, immediate load, extraction socket, immediate or late, and any of those considerations of concern for anybody with respect to classification or special controls.

DR. BRUNSKI: Probably because I left early, I didn't come in, or didn't hear the end of that meeting in November, but my only concern would be that it seems to me we're leaving a fair amount to the FDA to decide, because just personally speaking, it isn't necessarily obvious to me that every single root form implant is equally well

substantiated in these various kinds of indications. You know, that's just my feeling about it. I don't have any objection in proceeding to group them the way we're grouping them, but the indication issue is something that I guess the FDA will have to handle in some respect if we're not.

DR. GENCO: Would you like to give--I mean, you could talk about a special control for--what would you like, implant in extraction sockets to be evaluated separately from healed ridges? Is that the kind of--

DR. BRUNSKI: Well, here's a question maybe for the FDA. I mean, if somebody came out with an implant and wrote down specifically, this has an indication for immediate loading, would the FDA be likely to want to see something in a guidance document form to substantiate that?

DR. RUNNER: Well, typically, in the past, we've approached those different indications with requesting clinical data. But as time went on, it was pointed out to us that many of these indications, like using a fresh extraction socket or immediate loading, were actually pre-amendments claims and, therefore, were allowed to be included in the claims for various 510K implant systems that are on the market. So that's how they came to be. If we felt it was something that was not pre-amendments, we would have asked for clinical data. But people kept finding more

examples of implants that were pre-'76 that were used in fresh extraction sockets or immediately loaded or were of a particular diameter.

DR. GENCO: But would there be--

DR. BRUNSKI: Even if it's pre-amendments, if the product comes along, you still may request data to substantiate its equivalent performance.

DR. GENCO: Does the panel--is there sufficient concern of that to articulate this in special controls? In other words, studies to be required as appropriate, for example, preloading, immediately loading versus delayed loading, fresh extraction socket versus ridge. John, do you feel comfortable? We can, I think, word that special control in such a manner to spell out some of these conditions that we're aware of now that you have concern about.

DR. BRUNSKI: I don't know if I'm arguing for that so much as I'm just making sure that there are existing mechanisms in a special controlled fashion that could ultimately be brought to bear should somebody at some point think that this is relevant. I mean, there's so many different indications and so many different kinds of implants that I think it'd be difficult for us to look at each one and start to craft language on that.

DR. GENCO: Okay. Would something like this, clinical investigation, as appropriate, would be required for unique applications, indications, design? Is that sufficient? I mean, that could be a special control, I think, Jim?

MR. ULATOWSKI: We would retranslate that probably as far as the special--well, in the sense that the special control is a guidance document, and in the body of the guidance document, we would accommodate those concerns.

DR. GENCO: Okay. With some specifics?

MR. ULATOWSKI: Right.

DR. GENCO: Okay. Yes, Dr. Jordan?

DR. JORDAN: In these special controls, will you be asking the manufacturer to do the studies or would you be asking them to contract with someone to do it independently?

DR. GENCO: I think that's up to the manufacturer. As long as they're good studies, whether they did them in house or contracted with universities or what have you, I don't think that's--

DR. JORDAN: Well, sitting here in the consumer's seat, I don't share the opinion that we've heard lots of good studies here today. We've heard a lot of studies. I find it difficult to form some out. I don't know what success means. In some studies, there's a whole variation.

You have a ten-year study and five people have been in the study for ten years. That's not a ten-year study to me.

So I think somewhere, if we're going to start requiring this to happen--I mean, intuitively, class II doesn't bother me, because intuitively, and I'm being intuitive, too, I haven't seen many people running around complaining about their dentures or their prostheses not working well.

But in terms of an objective study, I think if one is going to rely on it, there needs to be better controls than I've seen today in terms of the quality of research that's going to document it and I would not want to just say, let the manufacturer, who has an obvious interest, who's both the dentist sometimes and the manufacturer, too, be the one to also provide me with the data. I'm going to guess what the data's going to be in some of the cases.

DR. GENCO: Dr. Runner, do you want to address that?

DR. RUNNER: Unfortunately, that's the way the agency works, in that we give the responsibility for the studies to the companies and we assume that the data that is provided to us is valid. If we have any questions about the validity or the truthfulness of the data, we have methods for investigating that. But we go by the assumption that

all data provided to us is valid and above board.

MS. SCOTT: If I can add to that, the panel can outline clinical study recommendations or clinical protocol that the panel would like to see in a guidance document that FDA produces in terms of what type of study protocol is recommended for these clinical studies in order to provide the type of data that's necessary to evaluate the devices. So that may help, too.

DR. RUNNER: And the guidance documents that we already have have specific testing requested, so that there are parameters as to the type of testing we would request for bench testing, coating characterization, et cetera.

DR. JORDAN: I may misquote, and I apologize if I do, but I do recall in some studies, some of the major presenters, the majority of the data were done in private doctors' offices. I'm a private physician as well as working at a medical school and I do data also from my office as well as the medical school. There is no question that what I can do in my office is much easier than what I would have to do if I go through an IRB in a medical school. I think if you're going to put this responsibility back on the manufacturer, then I think there should be some university, some independent IRB regulating this and not just my company saying, I've done this data.

DR. GENCO: I'm familiar with some of these guidance documents, having been involved in their drafting, and I know that, as Susan said, there are suggestions or requirements that they be independent, at least two independent, and they be multi-center. Of course, I think every one of them goes through the IRB. Even though they're done in an office, there are independent IRBs that if you're not associated with the university, you can hire an IRB to approve them. So I think they would all be done according to the Geneva Convention.

I mean, obviously, we would want that in the guidance document. I can tell you it's probably in the guidance document, but we can reiterate that. We can reconfirm that. So are there any other recommendations you'd make? Independent means there's PI who's not a member, not part of the company. He or she may get a grant from the company to do the study, but that PI is an independent operator and they're multi-center and some of the--

DR. JORDAN: Well, multi-center, and three different private doctors' offices is multi-center. I think a university should be involved somewhere with that.

DR. GENCO: Okay. So you would like to add multi-center, including at least one of the centers, a

university center?

DR. JORDAN: Yes.

DR. GENCO: I think we can add that to the guidance.

MR. LARSON: A comment, though.

DR. GENCO: Yes.

MR. LARSON: I think that does fly in the face of even the regulations in terms of the definitions of valid scientific evidence. FDA has a lot of mechanisms to monitor, to audit studies. They have a whole bioresearch monitoring unit, biometrics and surveillance. So they have the opportunity to review. If a company sponsors a study, the company in the regulations has very specific responsibilities. Now, I realize the regulations that I'm referring to are IDE regulations, but FDA can certainly apply those standards to any study that they're looking at. So I think that the idea that a priori a study sponsored by a company is suspect, I think is inappropriate.

DR. JORDAN: I didn't say a study sponsored by a company is suspect, but some can be. I will certainly say on the record, I could pick the data apart from some I've heard today and yesterday, and I think if we're going to now allow this to be a class II, there should be more controls than we've had and I see nothing wrong with any study having

at least one university-associated study being involved with it.

MR. LARSON: But I think it would be the first ever FDA regulation or guidance that would specify that.

MR. ULATOWSKI: I would agree with your comment, that such a restriction would be unique, unless--only if there was some particular aspect of these particular devices that demanded some clinical study requirements in order to assemble valid scientific evidence. But otherwise, sponsor manufactured and conducted studies are a fact of life in devices and in drugs and in biologics and there's adequate safeguards with regards to bioethics and the conduct of research that are in place.

MR. LARSON: Just one more comment on that.

DR. GENCO: Sure.

MR. LARSON: I think a lot of what we've seen today, some of the studies are studies that were done in preparation for the possible call for a PMA and were done to those standards. Others are not. I don't think we should fault the companies for presenting whatever data they have because they were asked to come with whatever data they have, and some of it is better quality than others. But if a company is asked specifically by FDA to present in a submission clinical data, FDA has a lot to say about how

they present that, what kind of data they gather.

DR. JORDAN: Remember yesterday?

DR. GENCO: Okay. Shall we proceed? I think we can revisit this issue when we talk about special controls if we decide to reclassify.

Willie?

DR. STEPHENS: I have one recommendation. I think that this application ought to refer specifically to implants that are done as two-stage and implants that are going to be--that immediate loading of implants ought to be a separate application because I think that's a fundamental difference and what we're looking at is with endosseous implants at this point. So I think that this ought to apply specifically to implants that are not loaded immediately.

DR. GENCO: So you're saying that--

DR. STEPHENS: There should be a special control, I guess--

DR. GENCO: Oh, all right.

DR. STEPHENS: --but we ought to be specific about that.

DR. GENCO: So that you're reiterating John's point, in a sense--

DR. STEPHENS: Yes.

DR. GENCO: --that the special control for

clinical studies should spell out that those for immediate loading be specifically tested under those conditions.

DR. STEPHENS: Yes.

DR. GENCO: Diane?

DR. REKOW: I have a little bit of a concern for non-growing patients, and I don't know that I've seen any data about that, so I'd like something someplace said about that and I'll let you wrestle with where that goes.

DR. GENCO: I think that could come in the clinical guidelines, that special consideration be given to adolescents and young patients who are growing in these studies, or you would like to limit them to non-growing patients?

DR. REKOW: I'd like to hear what the rest of the panel has to say.

DR. GENCO: Okay.

DR. REKOW: I mean, maybe they're close to the end of their growth. Maybe they're--

DR. GENCO: We are writing these special controls. Are we agreed to reclassify? Does anybody disagree? That is, the root form the way we've defined it, which is fairly all inclusive? Does anybody feel uncomfortable with that?

[No response.]

DR. GENCO: Okay. Then I would--does anybody want

to make a motion? Yes, Mark?

DR. PATTERS: I move to grant the petition and reclassify root form implants as class II.

DR. GENCO: Does anyone second that?

DR. RUNNER: I'm sorry.

DR. GENCO: Sure.

DR. RUNNER: Just for a point of order, we're not actually considering a petition. It's just reclassifying. Although there was a petition, this isn't specifically considering the petition.

DR. GENCO: So the motion is to reclassify root form implants in this all-inclusive definition as class II medical devices.

DR. HEFFEZ: I second it.

DR. GENCO: Willie?

DR. STEPHENS: No, I almost wonder if we ought not say that it is for adults, in adults, or--we can do that?

DR. GENCO: I think we're all agreed, also, there will be controls. So the logic to me would seem to be to vote to reclassify and then get into the controls in some depth, the three levels of controls, if we wish to recommend those three levels.

Tim?

MR. ULATOWSKI: I have a comment, or there was a

question about if a product has a 510K. Right now, it's been cleared under a 510K and the panel agrees hypothetically to move products to class II of this type that we're discussing right now. If there's a paucity of data on a particular type of implant that was nevertheless cleared under 510K, can we go back and get that data?

Well, I think you've got to consider the totality of the group that you're considering and understand from your experience and knowledge and background exactly everything that falls in that group. It may not necessarily be required to go back and get data, depending on your experience as clinicians, but it'd be unlikely that we'd see, for regulatory purposes, to see additional data if you put them all in the same bin.

DR. GENCO: Okay. Thank you for that clarification. So we're ready now for discussion on the motion, which has been seconded, to reclassify the--recommended reclassification of the endosseous root form implants in this most generic, general description, including all that we've heard today, as medical device class II. Discussion?

DR. REKOW: Can I ask a question?

DR. GENCO: Yes.

DR. REKOW: In light of what Tim has just said,

does that mean that we could still request some more data from some of the groups that haven't really provided a lot of data, or does that mean that, across the board, some people get lucky?

DR. GENCO: Tim, do you want to answer that?

MR. ULATOWSKI: Well, if you've got some residual concerns, I think you've got to deal with that as far as whether you want to lump or split, leaving an open concern for the industry for some additional follow-up studies for consideration. But I think as you recommend for reclassification, you are--everything that's in that bin is going to move to wherever you want to put it, and so you've either got to decide to lump or split, I think, at this point in time.

DR. REKOW: But if the controls include some performance data--

MR. ULATOWSKI: Well, that's primarily for new products coming down the pike.

DR. REKOW: That wouldn't apply to anything that--

MR. ULATOWSKI: That's not to say that they won't be studied, but it would be for regulatory purposes for new products coming down, to see whether or not they would be substantially equivalent to what you're lumping into that bin.

DR. GENCO: Jim?

DR. DRUMMOND: I think my interpretation of this is that if something's new enough that we're not heavy with clinical data, if we group them all together and pass them, we can't get the data. Is that what you're saying?

DR. RUNNER: Tim, are you saying that--what we're saying is that the things that are already cleared for 510K, if you classify them into class II, they're going to remain in class II and cleared and no additional data will be required. However, when something new comes down the pike, when somebody comes in with a new application, we will then be able to apply the special controls. The ones that are already cleared are going to stay cleared as class II.

MR. ULATOWSKI: Of course, those that are put into class II, the special controls that we define, may include also something like labeling or--and then all those products move to class II under the reclassification, would have to comply with the labeling special control, for example.

DR. GENCO: Could you give us an idea of what you've required for 510Ks for implants, endosseous implants? Maybe that would help. For example, do you require that they be tested in adults, not in children?

DR. RUNNER: Most of the 510Ks that have been cleared do not have clinical data associated with them

because they were pre-amendments class III devices, and therefore the companies were pulling together that clinical data. We do require complete chemical composition, complete characterization of the coating as described before, mechanical bench testing of the implant and the abutments. If we find that there's something that is unusual in terms of its design, we have required clinical data. But by far, the majority do not have clinical data.

DR. GENCO: Mark?

DR. PATTERS: I don't think we should lose sight of the fact that we're classifying a generic device. Now, some particular devices in this generic classification are very well studied. Some are not that well studied. But it really doesn't matter. It's a generic device of an endosseous implant, not a particular company's endosseous implant.

MR. ULATOWSKI: That's absolutely correct. And again, once you reclassify, there's products that are legally marketed right now and you're going to reclassify them class II. They're still legally marketed. They don't have to come back again to us. They don't need another 510K. So they're out there, they have to comply with the special controls. The data business would not apply, I would estimate.

DR. GENCO: So you have approved by 510K those devices that have demonstrated to your satisfaction that they were substantially equivalent to the PMA, or to the pre-amendments, excuse me, devices?

MR. ULATOWSKI: Right. And by saying originally class III, the panel was originally saying, well, we don't know enough and so we want to have a PMA and get the clinical data. But now if you move to class II, you're saying what we've heard today and what's been submitted to us by companies gives us enough confidence that this bin we have defined, there's enough data supporting it. It's the alternative method.

DR. GENCO: So let's go back, then, to our definition of what these root form endosseous implants are. Do you still want to include all of those in that definition, given this new information?

DR. DRUMMOND: I'll go back to my original question. Do all the implants we discussed today have clinical data that follows "normal" standards for clinical data that some of them do have? I think I've already answered that.

DR. GENCO: Tim?

MR. ULATOWSKI: It was a good comment from a

staffer that there were some discussed today that were still pending clearance, so they're not okay. They're not--

DR. GENCO: What happens to them, if they're pending clearance? If it was--

MR. ULATOWSKI: Well, if they're still pending, if we reclassify, they'd still be subject to evaluation and decide whether they're equivalent or non-equivalent.

MR. LARSON: And the special controls--

MR. ULATOWSKI: If they're equivalent and you should so reclassify them, they'd be subject to the special controls.

DR. GENCO: Okay. So we recommend reclassification. You make the decision. So if something's pending, you're going to hold off until you make that decision?

MR. ULATOWSKI: No.

DR. GENCO: So something could get in between--

MR. ULATOWSKI: Wherever we're at at that point in time, whatever the standing requirement is. So the 510K, be it PMA, be it whatever--

DR. GENCO: Okay. That's only fair. All right. So it could very well be that some of these that are in now would get approved under the old condition and not--because the decision for a class II may not take place immediately.

Yes?

MR. LARSON: Just for perspective, though we recognize that the quality of clinical data varies rather widely and there may be some that don't have clinical data, I think we need to think as to the whole bin that we're putting these into. Have there been disasters? I think those who are in the clinical and research community can better judge that than I. But are there disasters lurking out there or is there a reasonable level of confidence that the bin is okay?

DR. GENCO: Yes. One of the questions we have to answer is, does the device present a potential unreasonable risk of illness or injury. Does anybody want to address that? I mean, if that's an important issue. Does anybody think that there is unreasonable risk of injury? Then you think there isn't, so we've answered no to that.

Do you think we have sufficient information that we can establish special controls for all new devices in this category to provide reasonable assurance of safety and effectiveness? I mean, that's another issue. If you do, then you would vote for class II.

[No response.]

DR. GENCO: Okay. Further discussion? Are you ready for the vote?

DR. BRUNSKI: Maybe as a suggestion, I mean, actually, you started to look at this questionnaire. Isn't the process of arriving at the classification requiring going through this questionnaire, rather than just voting?

DR. GENCO: Well, let's do that as part of the discussion, then. Is the device life-sustaining or life-supporting?

DR. PATTERS: No.

DR. GENCO: No? Is the device for a use which is of a substantial importance in preventing impairment of human health? Is it of substantial importance in preventing impairments of human health? In other words, is it of substantial benefit to the patient? That's the way I interpret that.

DR. PATTERS: Yes.

DR. GENCO: Yes. Does anybody disagree?

Does the device present a potential reasonable risk of injury or illness? We answered no to that.

Is there sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness? Remember, if you answer yes to that, you go to class I.

DR. PATTERS: No.

DR. GENCO: Okay. Is there sufficient information

to establish special controls?

DR. PATTERS: Yes.

DR. GENCO: Okay. Therefore, we are at class II, which is, is there sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness. If it's yes, then we would be recommending classification in class II. Is the answer yes? Does anybody disagree with yes?

[No response.]

DR. GENCO: Okay.

DR. RUNNER: Can I ask one question?

DR. GENCO: Yes.

DR. RUNNER: Can I clarify that you are including all root forms, all implants that are root form with special retention features and root forms that are temporary in this grouping?

DR. GENCO: Yes. I mean, I've asked that question, I think, three or four times. Let's ask it again to make sure everybody's comfortable with that. Remember, some of those don't have the data that others do.

DR. DRUMMOND: I guess I'm not comfortable until we get the data, and what I'm hearing is if we don't get the data, they'll still get improved anyway because we're reclassifying all of them.

DR. GENCO: Because they're in the process or have already been classified?

DR. DRUMMOND: Yes.

DR. GENCO: Mark?

DR. PATTERS: You really can't separate those unless you believe that they are for a different intended use. If you do, then you can separate them. But if they're for the same intended use, the data is not the issue. It's a generic device we're classifying. Some have good data, some do not.

DR. DRUMMOND: That's not my interpretation. My interpretation is some of them don't simply have the clinical data and it's more testimonial than clinical. That's what bothers me.

DR. PATTERS: But that's not the issue. It's a generic device and the question is, is there enough data about this generic device to feel that the device is safe and effective? That's the only question, in its intended use. Now, if you believe the device has a different intended use, you could look at that device differently. Correct me if I'm wrong here.

MR. ULATOWSKI: Mr. Chairman?

DR. GENCO: Yes?

MR. ULATOWSKI: There's a number of

classifications that are in the regulations that are split, same device, different characteristics or uses. It depends where the panels have felt this particular size of device or particular use of a device or whatever should be a different class than another size or use. So intended use alone is not the only factor that may be considered in the classification. There can be other factors.

DR. GENCO: So the issue is, of these unique ones that we heard today, and maybe unique is not the term, but let's be specific. For the Sendak mini-temporary, for the Tronics Oral bicortical screw, and for the Sargon, are they sufficiently different than the other implants which we're reasonably comfortable with, endosseous implants, to require special studies or special classification? Leslie?

DR. HEFFEZ: I think the one currently classified as a special retention device, that's the Sargon, should be--is misclassified. I believe it should be placed in a root form. That's my impression.

DR. GENCO: So you would want to keep it in with what we're talking about as root form--

DR. HEFFEZ: Yes.

DR. GENCO: --and what we're going to vote on?

DR. HEFFEZ: Right, and I would say that we have not considered an implant as a special retention device.

That's my impression.

DR. GENCO: Okay.

DR. MORGAN: Can I ask one question?

DR. GENCO: Yes.

DR. MORGAN: If we classify everything as class II, can the things in the bin have different special considerations or does that get applied across the board? Like do we ask for special considerations that were unique to different types of implants that were all generically root form implants?

DR. GENCO: Yes. I would imagine for a temporary one you could ask the question Willie asked. Well, how long is temporary? The studies should be under temporary use.

DR. MORGAN: So would that kind of answer James' question that some people have good clinical data that support being class II where others did not? Would that satisfy that?

DR. GENCO: Yes, but remember, some of these already are approved or are in the bin.

DR. MORGAN: So once it goes in the bin, it's just--

MR. ULATOWSKI: Mr. Chairman?

DR. GENCO: Tim?

MR. ULATOWSKI: Yes. Reading from the

regulations, 860.3(i), generic type of device means a grouping of devices that do not different significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness. So there's a number of qualifications.

DR. GENCO: So that the answer to Andrea's question is no, you really--they should all be amenable to the same set of standards, special controls.

MR. ULATOWSKI: Whatever you place in the bin should have the same--

DR. GENCO: Okay. That's a very important distinction, then.

MR. ULATOWSKI: --finding.

DR. GENCO: Right. In other words, you should feel comfortable that each one of these we've defined as endosseous will be subject to the same set of special controls. Okay. I'll ask again. Are there any of those that you want to remove from this definition? John?

DR. BRUNSKI: Well, yes, I think I would, but just one other clarification. In other words, if ones are in the hopper now awaiting 510Ks or already have one and we reclassify the IIIs to the IIs and they're in that bin, does

that mean that existing guidance document that exists right now can't be changed with respect to any of those? I'm wrong about that, right?

DR. RUNNER: The ones that have already been cleared have been cleared according to the guidance document and other recommendations. The ones that are in the bin would be cleared according to the guidance document. The guidance document can always be changed at some point through appropriate methods, if it's felt necessary.

DR. BRUNSKI: So all the ones we've heard about today have basically been cleared, I guess, with--

DR. RUNNER: There are a couple of them that we heard about today that have not been cleared.

DR. BRUNSKI: Well, for example, the Sargon, I mean, to me, in my mind, I mean, mechanistically, it's a very different active device. It's a device that actively is turned. It presses on the bone, et cetera. I mean, I agree with Dr. Heffez that in terms of some of the risks, some of them are the same, but others may not even be really well known yet.

DR. RUNNER: And that device has been cleared and it was cleared with clinical data.

DR. BRUNSKI: It was?

DR. STEPHENS: If we were to put the Sargon in a

category of special retention, we could do that because we wanted additional different information, but it could still be a class II device, is that correct?

DR. GENCO: So are you suggesting that?

DR. STEPHENS: I would be more comfortable with that, yes. I think that I would be comfortable with the Sargon being--I wouldn't have any problem with it being a class II, but I would like it in a classification as an implant with special retention features.

DR. GENCO: So endosseous root form with special retention, that's a different class II?

DR. STEPHENS: A different class II.

DR. GENCO: Okay. What do we do with that? Do we come up with special controls for that class II? So you have some special controls unique from the special controls for the others in that category?

DR. STEPHENS: I think that we would want studies to--we could request additional studies for it.

MR. ULATOWSKI: There's possibilities for post-approval, post-clearance investigations or follow-ups. The panel may recommend in that area. I'm just saying that the product's going to be out there if you put it into class II.

DR. GENCO: So, let's see. Let's play that

scenario. Let's not just talk about Sargon. Let's say a device with special retention is already on the market, has 510K approval. We put it as a class II device into another category with specific special controls. What happens now? Will that device be now subjected, required to come up with these--

MR. ULATOWSKI: It has to meet the special controls. It's on the market.

DR. GENCO: Even though it's on the market?

MR. ULATOWSKI: It's on the market.

DR. GENCO: So this post-market application of special controls based upon this decision?

MR. ULATOWSKI: There is an element of that in the special controls described. You can identify something there for study.

DR. GENCO: Okay. I think before we do something like that, we ought to have some very good idea of what the issues are. Willie, do you want--

DR. PATTERS: That's true for all devices, though, not just those with special retention features. They still have to meet the special controls--

MR. ULATOWSKI: If you're class II, you'd still have to meet the special controls, but the special controls can vary.

DR. GENCO: Even though they've been on the market for a number of years?

DR. PATTERS: That's correct.

MR. ULATOWSKI: Right.

DR. GENCO: So if the special control is a unique study, let's say some study in--a unique study--

MR. ULATOWSKI: Knowing it's a follow-up. It's not a pre-approved study.

DR. GENCO: Are you comfortable with that, then? Okay. Good. So I hear that we're lumpers and not dividers at this point.

George, you had something to say?

DR. McCARTHY: I just wanted to throw in my two cents worth on the Sargon implant. It's an implant that has moving parts. It basically, by the developer's own words, it is capable of doubling its diameter. So that, to me, makes it a really unique implant.

DR. GENCO: Would you be comfortable with special controls for that sort of implant but keep it in the same group of endosseous root form--

DR. McCARTHY: Yes.

DR. GENCO: Okay. It looks like we're closer to a vote. Does anybody want to discuss this further? Jim? We're going to vote now to recommend classification in class

II for the whole lot of what we've heard and some that we may not have heard about.

MR. ULATOWSKI: So are you collapsing the four categories?

DR. GENCO: No. Oh, excuse me. We're only talking about the endosseous root form. We're not talking about the blade or--

MR. ULATOWSKI: Okay.

DR. GENCO: What was the other one? Excuse me. In a way, we're collapsing the special retention that we heard about and the temporary into the root form and leaving the blade out. Is that clear? Both Mark and Leslie, who have made and seconded, you're clear? Okay. That's clear.

MR. ULATOWSKI: Good.

DR. GENCO: Okay. Are we ready for the vote, then? Thank you, Tim, for pointing that out.

I'm not exactly clear of the voting members here. I think I've got them all down, but maybe, Pam, you can help me here. Let's start, then. I've got them in a list here. Let's start at the back end of the list. Dr. Rekow, what is your vote?

DR. REKOW: I approve.

DR. GENCO: Dr. Morgan?

DR. MORGAN: I agree.

DR. GENCO: Dr. Heffez?

DR. HEFFEZ: I agree.

DR. GENCO: Dr. Brunski?

DR. BRUNSKI: Agree.

DR. GENCO: Dr. Patters?

DR. PATTERS: Agree.

DR. GENCO: Dr. Stephens?

DR. STEPHENS: I agree.

DR. GENCO: And Dr. Janosky?

DR. JANOSKY: Agree.

DR. GENCO: Okay. Thank you very much.

The next step is to discuss special controls. Now, I just put out a suggestion that, from what I heard today and previous experience, there are at least three types of controls. One is these technical controls, like standards for materials, standards for benchtop testing, and then manufacturing standards.

Is that well established? Do we have to do much with that? Is there a committee--Floyd, help us here--that has already discussed this? Is that in progress? Is it done? Where are we with those technical aspects?

MR. LARSON: I wish I could say that it's all done. There are aspects of it that are being dealt with, but, for example, on x-ray diffraction analysis of HA

coatings, there is a task group that is trying yet to develop a standard even for the method. It's a little more specific and probably closer with regard to fatigue testing of dental implant assemblies, and that is encouraging in that there is an ISO working group that is well along in the process of developing a standard for that. But I cannot say that that standard exists.

DR. GENCO: So one option would be that we would recommend voluntary standards, such as the ASTM and the ISO standard.

MR. LARSON: Yes. Now, for the materials, the voluntary standards are well in place.

DR. GENCO: Okay.

MR. LARSON: I mean, for titanium, for example, for the titanium alloy.

DR. GENCO: Right.

MR. LARSON: So we're quite accustomed to using those standards in our communication with FDA on 510Ks.

DR. GENCO: Okay. Let's deal with that. Does anybody have any problem with that, voluntary standards for the materials using the ASTM and ISO standards recommendations? Yes?

DR. REKOW: What happens when I want to introduce a magic polymer as my blade implant? Sorry.

DR. GENCO: No. That's a good question.

DR. REKOW: I mean, on root form.

DR. GENCO: Yes, root form. I think what we're talking about here, and we probably should be specific, are titanium and coated titanium, hydroxyapatite coated titanium. We haven't really heard of any other--

MR. LARSON: And titanium coating.

DR. GENCO: Yes. Titanium, titanium coated, and hydroxyapatite coated titanium. Have we heard of any others? I think we can say that, I think, specifically. Those are the materials that we're talking about with respect to this form, and as a matter of fact, we can add that to the definition. The definition of root form includes those made of titanium with either titanium or hydroxyapatite coating. So if somebody came with a new material, glass or whatever it is, that would be a very different situation. Mark?

DR. PATTERS: Would it be incumbent upon them to show that their material was substantially equivalent, and that's the FDA makes that interpretation.

DR. GENCO: Okay.

MR. ULATOWSKI: You want to retain flexibility in product development. A corollary to this standards discussion is at FDA, there is a new law FDA is working

under and part of that new law deals with the recognition of standards and the use of standards by the industry and that will be picked up, I think, pretty quickly by our staff in recognizing certain standards. But the element of that use is the voluntary nature of the use of those standards.

DR. GENCO: Okay.

MR. ULATOWSKI: Using them speeds the process, but you may choose not to use those standards and do something else.

DR. GENCO: Okay. Is everybody comfortable with that, then, to use those voluntary standards that are already pretty much in place--

DR. REKOW: For those materials.

DR. GENCO: For those materials. What about the benchtop? Floyd, what is the status there? These are in progress to be developed?

MR. LARSON: Some of them are in progress. I can't say that it's comprehensive even with regard to being in progress. I'd say that the one that I think is the most relevant to this right now is the ISO fatigue testing standard and you've just put a fire under me to help move that along.

DR. GENCO: Is there any specific recommendations in terms of the benchtop testing that we should address?

DR. PATTERS: Doesn't the guidance document address that?

MR. ULATOWSKI: Yes.

DR. PATTERS: The existing guidance document.

DR. GENCO: It does?

MS. SCOTT: Yes. There are recommendations in the existing guidance documents. However, if the panel believes that there are certain specific recommendations that may not be included in the guidance documents or that they want to reiterate, you should state that today.

DR. GENCO: Yes?

MR. LARSON: Floyd Larson. I haven't been saying my name. Sorry. One of the problems with the kinds of standards that are developed in the voluntary arena is that the first stage is to get a standard that specifies a method in common. It's sometimes quite a long process beyond that to get a performance standard.

For example, when I say we're developing a standard for fatigue testing, we're not saying what's good and what's bad. So the combination of that voluntary standard on the method with FDA's requirements on the values to be obtained or their good engineering judgment on a case-by-case basis is what we've been going on and I think that is appropriate for this.

DR. GENCO: And this panel really can't add much to that. So we'll go with what is in the guidance documents and--yes?

DR. BRUNSKI: Well, when it comes to fatigue, I was just going to ask that I would like to see some flexibility in the guidance document to anticipate various types of active retention mechanisms, like we've been confronted with now. In other words, the fatigue standard that I presume you're working on is largely concerned with testing abutments and axial loading, bending loading. It doesn't really necessarily deal specifically with some sort of development which is maybe coming out into the bone and may also be, at least as a thought question, being concerned with fatigue of those parts.

So the current guidance document doesn't specifically break that out, but yet, I mean, I would just like to suggest that that's an area where we might want to think about other kinds of fatigue tests that might be relevant for certain other kinds of implants than we see right now.

DR. GENCO: Yes, Dr. Larson?

MR. LARSON: For the panel, I think that's particularly difficult because I don't think even you and I could anticipate or even for an existing implant figure out

how to do that kind of fatigue testing. With the testing that we've done so far, just managing to somehow test an implant, not the structure on top of it, is difficult.

DR. BRUNSKI: But by analogy, I mean, before we had HA coatings, we weren't worrying about measuring bond strength of coatings to surfaces.

MR. LARSON: Yes.

DR. BRUNSKI: But then when they came on the market, that's now a test that's in the guidance document. So similarly, although maybe we don't have a lot of them right now, we might have a lot of implants sometime that have a lot of active internal gizmos.

MR. LARSON: And by no means am I suggesting that we shouldn't be concerned about that. I'm just saying that for the panel to make very specific recommendations would be impossible, I think. One of the issues, though, is FDA can, as they see these things coming, start asking for additional testing, I mean, but they have to do it when they see them.

DR. GENCO: So are we comfortable, then, with the recommendations for these benchtop standards as they are in the guidance documents and as they're evolving? Okay.

I think the manufacturing, that's pretty much up to the FDA and we're reasonably comfortable with that, the GMP and ISO standards.

Any other specific controls with respect to the technical aspects? Anything unique?

[No response.]

DR. GENCO: Okay. Let's go, then, to the clinical investigation guidances. As I recall, there's a long history of those guidances going all the way back to the early '90s and they're reasonably mature. They have had another iteration, at least with the American Academy of Perio and the FDA and several other organizations. Is there anything specific that this panel might want to add to those?

I can tell you, overview, that the guidances are for two fairly large, 50-patient studies, independent, multi-center, outcomes being survival, using the criteria that we've heard today of freedom from pain, freedom from infection, freedom from radiographic change, and freedom from mobility.

I heard something about in non-growing individuals. Do we want to make sure that's in the guidances for these special--for the studies?

DR. REKOW: I'd feel a lot more comfortable if that were the case.

DR. GENCO: Has this come up as an issue? How about in the studies of ectodermal hyperplasia? What was

the situation there? George, had those kids stopped growing or were they--

DR. McCARTHY: No. Actually, we probably at NIDR probably placed more implants in kids than anybody in the world. I think we've placed about 700 in adolescents and children and it really is site-specific. Of course, these are unique individuals, too. We sought patients who had--the fewer teeth they had, the better. We actually published, the youngest case in the English speaking, or actually in the world literature is three years and 11 months with a five-year follow-up that was published in the Journal of Pediatric Dentistry, I think, in May.

It really is very, very site-specific. The anterior mandible is a very safe place to place implants in kids four, five, and six years. In fact, SIU is continuing on with that with the Foundation for Ectodermal Dysplasia, placing implants.

However, in that same child that I just mentioned--these implants, by the way, in the youngest child, the implants were actually surgically placed in another place and he was referred to us for follow-up treatment. We did the second-stage surgery to uncover the implants and reconstructed them. The maxillary implants were, at age ten, were--we decided to put them to sleep and

not do anything with them because they weren't prosthetically useful. They were in the fore of the nose at the age of ten, so you can definitely get into trouble with placing them in very young kids. So it really tends to be very, very site specific and it just depends.

DR. REKOW: I would be comfortable if there's just some way that that has to be said, so the assumption is not that anybody can use them anyplace, any time, for any--

DR. GENCO: Is that a labeling concern?

DR. REKOW: Probably.

DR. GENCO: Okay. Maybe we can address it there.

DR. STEPHENS: Are you referring to a child without a syndrome who's missing teeth or more to these type kids?

DR. REKOW: No. I'm thinking--the thing that brought it to mind is, for instance, the missing laterals, an orthodontist that wants to put the prosthesis in early and get the kids all gorgeous and those sorts of things.

DR. McCARTHY: I think there's a party line on that, too. The maxilla, the anterior maxilla is a place where you can get into trouble because of the way the face grows.

DR. REKOW: So that was what prompted my thinking about it, and I haven't even thought about your--

DR. GENCO: Would a labeling caveat, such as for use in non-growing individuals, particularly not to be used in maxillary anterior--

DR. McCARTHY: That certainly would--the trouble you're going to run into is what determines non-growing. It even varies by sex. I think the recommendation is that you can get away with maxillary interior implants, for example, lateral incisor in females at about 17 or 16 and when the boys, you should wait a little longer.

DR. GENCO: Yes, but aren't there ways of doing that? I mean, they may not be--

DR. McCARTHY: Yes. That would be a warning label, essentially.

DR. GENCO: Yes. I mean, if you use the term non-growing, that puts the onus on the clinician to determine that they're non-growing. I mean, I think there are ways of doing that that are reasonable. They may not be precise.

DR. REKOW: Yes. I'm real comfortable with that.

DR. GENCO: Okay. Good. So that would be labeling, then.

Let's go back to the clinical studies. From what I've just said about the clinical studies, is this fairly accurate, Susan, Tim, Pam, the overview that they're--

MR. ULATOWSKI: We understand where you're coming from.

DR. GENCO: Two 50-patient studies, independent, multi-center, outcomes being success, and we've heard over and over again that life table analysis for success be determined, to determine the proportional success every year or at every interval, fairly straightforward. We heard many of those studies today.

Anything else that you'd like to see? Cause of failure, I think we emphasized that, a table of cause of failure, fracture versus infection versus occlusal overload. Consideration of patient selection, risk factors, inclusion, exclusion criteria. Yes?

MR. LARSON: Floyd Larson. I want to go back to the criteria for success that you mentioned. You mentioned four criteria, one of them being mobility. While that's very well established since the earliest studies as maybe the principal criterion, we ought to give some thought to the increasing use of cemented restorations and the appropriateness of mobility determination on individual implants.

DR. GENCO: Yes. I think somebody dealt with that, one of the last presentations this afternoon. I apologize I don't remember exactly who it is to give you

credit. But the consideration was that it would be a mobile implant with the abutment off.

MR. LARSON: Right, but the point is that if you are dealing with the real world situation of cemented multi-unit restorations, there are going to be a lot of prostheses which are not amenable to that mode of examination and there are certainly, and again, I'm obviously not a clinician, but clinicians who deal with those kinds of cases have other ways of assessing whether or not the implant is successful.

DR. GENCO: That's right. I think the other three criteria often will be seen, and the fourth one we discussed, and the fifth was the alveolar crestal height loss, one millimeter in the first year, 0.8 cumulatively over the next four years. So any one of those--

MR. LARSON: As a mean for the system.

DR. GENCO: Well, no, per tooth.

MR. LARSON: No.

DR. GENCO: That is, an implant failure is defined as one that has above those thresholds of interproximal bone loss. I think--we can argue about that, but I think we might leave the clinicians who've designed the studies to tell us what their measuring.

MR. LARSON: Okay, except that half the Branemark

implants would have been failures.

DR. GENCO: Well, as I say, I don't want to second guess those guidances. The committee spent many, many months talking about those things. But there is a radiographic criteria. There's a mobility criteria. There's a pain criteria. There's an alveolar crestal criteria. There's an infection criteria. Some of the infection criteria require suppuration. Some don't. And then there's a whole set of periodontal criteria that could be applied, also.

Okay. Are you comfortable, then, with those guidances the way I've stated them--I hope I've been reasonably accurate--as the clinical trial guidances?

[No response.]

DR. GENCO: Okay. Let's go to--we're not considering patient registries or device tracking, are we? Is there any necessity for that?

[No response.]

DR. GENCO: Let's go to labeling. We've heard one consideration for labeling and that is the recommendation they not be used in non-growing individuals, particularly in maxillary anterior. Any other labeling considerations?

DR. HEFFEZ: Leslie Heffez. The immediate implant loading versus non-immediate loading, have we or are we

going to consider that? I do think that that's distinctly a different hat. Most of these, we're considering a delayed fashion.

DR. GENCO: Okay. Do you want to add that as part of the guidance, that if the indication is going to be for immediate loading, that they be tested in these clinical studies under those conditions, otherwise the claim can't be made? Is everybody comfortable with that? Does that make sense from the point of view of the FDA?

[No response.]

DR. GENCO: Okay. So if somebody's going to make that claim, our implant is super-duper for immediate loading, that the clinical studies support that. Okay.

Any other special controls? Yes?

DR. MORGAN: You mentioned education as part of it.

DR. GENCO: Yes.

DR. MORGAN: I was thinking, for some of the implants that--like the Zygomatics implant where it's very technique sensitive, that that might be a special control for that specific implant.

DR. GENCO: Okay. Willie?

DR. STEPHENS: The manufacturers already have that built in. They require their own training course before you

can purchase and use the implant already.

DR. GENCO: Okay. Any other special educational controls that you think should be applied? Tim?

MR. ULATOWSKI: I just want to clear up my own mind on one aspect, and that is you mentioned the clinical study aspect and the two study, 50-patient aspects, and your consideration was in regard to that for new products coming down the line, prospective studies, so on and so forth. I just wanted to see if there was a residual concern about the database on any existing products that you have in your bin and was there still a mind to get some data on any of those products in some way, shape, or form?

DR. GENCO: Another way of asking that might be, of any of the products that we've heard about or know about, would you lessen that standard for clinical study, the temporary--

MR. ULATOWSKI: No. I'm saying, would you increase--

DR. GENCO: Oh, increase that?

MR. ULATOWSKI: Add a class to expectation for certain types of devices.

DR. GENCO: The one we've heard--

MR. ULATOWSKI: But that's difficult because you're kind of defining in this bin, in one bin for

classification.

DR. GENCO: The one we've heard was for the claim of immediate loading to be tested under those conditions, but it could be that same protocol, that same two, 50-patient multi-center study. That's what I'm hearing. Leslie?

DR. HEFFEZ: What are the ones that are in the bin? Are those only the presentations that we received, or are there others that are in the bin that we haven't heard about?

MR. ULATOWSKI: Everything that's in the bin right now is what's been pre-amendments or substantially equivalent within the root form devices you've characterized.

DR. RUNNER: That original grid that you collapsed was everything that we had pretty much--

DR. GENCO: Any feelings, then, about additional studies for any of those, the "special retention" and the temporary? Tim is asking, do you think there need to be more studies of those than the guidances that I outlined?

DR. HEFFEZ: I think to place an implant in the category of special retention device, I think the manufacturer should indicate or should prove that the special retention device is the primary reason for

classifying it that way. In other words, that you have another implant that is retaining, that it's just an auxiliary portion of the implant as opposed to the primary part of that implant.

DR. GENCO: What we've done is collapsed it, so I guess it's not special retention anymore.

DR. HEFFEZ: Yes.

DR. GENCO: But you're saying if one makes the claim, they should prove it?

DR. HEFFEZ: Yes.

MR. ULATOWSKI: If you're not differentiating any special controls, then we're going to be collapsing these things there.

DR. GENCO: But the point is, if somebody makes that claim, we've collapsed. But somebody wants to differentiate themselves and say, well, we have endosseous root form class II but we have special retention, don't you require that that be justified, that claim, clinically justified?

MR. ULATOWSKI: There'd be some additional aspects to the study.

DR. GENCO: Okay. So that's really a labeling and a claim justification, then, and that's covered. We've got that covered. Just like the immediate loading claim

labeling? Okay. Yes?

DR. REKOW: Did we or did we not take the moving parts implants out of this?

DR. GENCO: No.

DR. REKOW: I thought that we had done that before we voted.

DR. GENCO: No. It was in. I'm sorry if you didn't understand that. I thought we discussed it several times and people were comfortable that it was in. But I think the point of moving parts was made. The point of if the claim was going to be special retention is made, that it be justified by a study.

MS. SCOTT: Dr. Genco, could I just ask Mr. Ulatowski to clarify. Were you referring to additional studies for implants that are already cleared or additional studies for those coming down the pike?

MR. ULATOWSKI: Well, it's this bin question again. It's additional studies for those that are already marketed. I thought I heard a concern about some devices, but if that's gone by the wayside during the discussion, so be it.

DR. GENCO: Okay. Let's proceed. Any other special controls, now? Let me just reiterate. Performance standards are voluntary, both for materials and for bench

measures. We don't think that patient registries or device tracking is reasonable. Testing guidelines, that's the bench testing, I take it. Then the others is the clinical studies, and we talked about those. Those studies should be relevant to the claims made, and the labeling, the one labeling concern was to use in non-growing persons especially in maxillary anterior region. And then the last one was the education special control, particularly for the--well, for the teragoid implants. Any others? I guess not, just for the teragoids.

Yes?

MS. SCOTT: Dr. Genco, can you clarify for the clinical study special control that for all types of implants in this bin that come down the pike in the future or certain implants within the bin that the panel would recommend clinical studies for, only be as appropriate at this time.

DR. GENCO: I think we started off by saying as appropriate and I think we outlined a lot of the concerns. The concerns, let me go over those again, were immediate loading, the concerns for if a device had special retention claims that then there be specific studies required to substantiate those.

MR. ULATOWSKI: Pam is trying to get at under the

510K process, you can analyze a product by its descriptive features alone--

DR. GENCO: Right.

MR. ULATOWSKI: --and possibly render a decision if it's so similar without the need for additional clinical--for clinical data.

DR. GENCO: So what we're saying is if there's either something in the bin or something that comes down the pike that is a clone of something that's already been studied ad nauseam that there need not be further studies. Does everybody understand that?

[No response.]

DR. GENCO: Okay. I think that we're clear on that.

We have a series of questions to answer. If a regulatory performance standard is needed to provide reasonable assurance of the safety and effectiveness of the class II device, what is the priority for establishing such a standard? Now, this regulatory performance standard, define that for me. Have we defined anything like that?

MR. ULATOWSKI: No. None of the standard we are talking about are regulatory standards.

DR. GENCO: Okay. So that's not applicable.

For a device recommended for reclassification in

class II, should the recommended regulatory performance standard be in place before the reclassification? That's not applicable.

For a device recommended for class III, that's not applicable.

Now, number four, because of any potentiality for harmful effect or the collateral measures necessary for the device's use, can there otherwise be reasonable assurance of its safety and effectiveness without restriction on its sale, distribution, or use? Where are we with that one? That's no, isn't it? No restrictions.

Okay. Now, the supplemental data sheet--oh, it's yes.

MR. ULATOWSKI: There are some prescription use--

MS. SCOTT: Prescription use only type restrictions, things of that sort.

DR. GENCO: Okay.

MR. ULATOWSKI: Sometimes there are some other limitations on types of professionals that can use it, but--

DR. GENCO: So these can't be put in by non-professionals. It's prescription use, then. Okay.

Now, the supplemental data sheet, indications for use prescribed, recommended, or suggested in the device labeling that were considered by the advisory panel. I

think we did consider those. Any specific use, like immediate loading or specific retention or use in children would have to be considered either in the testing or in the labeling.

MS. SCOTT: Dr. Genco, if you could just formulate a statement as to the general intended use or indications for use for this type of device and the stated name for this device for the record so that when we go back to write the regulation, it will be stated.

DR. GENCO: These are endosseous dental implants and the use of these endosseous dental implants--let me try it and then the panel can help--is to replace missing teeth, to restore function, aesthetics, and phonetics.

MR. LARSON: Dr. Genco, jumping off from the existing regs might be a way to go. Obviously, we're narrower than that, but 872.3640, do you want that--

DR. GENCO: All right, please.

MR. LARSON: This is the existing endosseous implant description in the regs. "An endosseous implant is a device made of a material such as titanium intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function." So that's what we--

DR. GENCO: Okay. So we can get that into the--

MR. LARSON: Right, but that's not necessarily--we're narrower than that because we've said root form.

DR. GENCO: Right.

MR. LARSON: And we've also specified the material more precisely than "such as titanium". But it's a jumping-off place.

DR. GENCO: Okay. The generic device's endosseous root form implant made of titanium, titanium alloy, coated with titanium or hydroxyapatite. Is that--

MR. LARSON: Or not coated. Uncoated or coated with--

DR. GENCO: Uncoated or coated. Right.

MR. LARSON: And then you go into the "intended to be".

MR. ULATOWSKI: It depends on how you come out with the other ones.

DR. GENCO: Pardon?

MR. ULATOWSKI: It depends how you come out with the other ones, what the ultimate final regulation would look like, but it's right to start this way--

MR. LARSON: We don't have to actually write these words.

MR. ULATOWSKI: You can concentrate on the subcategory for now. What you've just said is an overlay, the introduction, if you will, to the classification.

DR. GENCO: Okay. Are there any risks to general health presented by the device? Does anybody know of any risks to general health? No?

[No response.]

DR. GENCO: How about specific hazards to health? In failures, you get resorption of alveolar bone. Dr. Krauser showed some examples. Is that a specific hazard? Infection?

DR. HEFFEZ: Leslie Heffez. I think it's dependent upon the patient's systemic condition. If the patient had a history of bacterial endocarditis, they're more at risk for developing bacterial endocarditis and the use of an implant might be, maybe not a contraindication, but a precaution that if it fails or shows evidence of failure, it may increase the risk of recurrent bacterial endocarditis. So I would say something to the effect that it's really contingent upon a patient's general medical condition but there's nothing specific to the implant that presents a hazard to the patient's health.

DR. GENCO: Okay. Any other specific hazards to health?

DR. REKOW: You might say, in addition to being the systemic condition, the general oral health of the patient, too. I think that that's--

DR. GENCO: So local infection related to general oral status?

DR. REKOW: I think so. But again, not the implant.

MS. SCOTT: Dr. Genco, I don't know if the panel wants to address this, but in the initial classification of endosseous implants, there were a number of risks that the panel, that the original classification panel identified that was published in the Federal Register notice, and I don't know if I can remember all of them off the top of my head.

DR. GENCO: Yes. I think we could look at this now again, five years later, seven years later.

MS. SCOTT: Right.

DR. GENCO: Are there any others? We're talking about infections such as subacute bacterial endocarditis, associated to the general patient condition which may increase, the risk may be increased, and local infection around the implant may be increased by local oral conditions. Is there anything else?

DR. BRUNSKI: This is John Brunski. See, I'm not

sure exactly how you're defining health, but I view this as these are specific risks associated with using an implant.

DR. GENCO: Right.

DR. BRUNSKI: Yes, you can lose some bone because of, well, as we've heard, inflammation due to bacteria, maybe overloading. The implant could fracture. You could hit some nerves. I mean, I'm not sure. Are we trying to specify risks that are associated specifically with putting an implant in?

DR. GENCO: Sure.

DR. BRUNSKI: I mean, those are some that come to mind.

DR. GENCO: Okay. So we've dealt with three types, then, infections such as SBE, local infection that results in bone loss and other tissue loss, and then nerve paresthesia, or nerve damage. How about sinus perforation?

DR. HEFFEZ: I would say sinus inflammation/infection of the sinus, perinasal sinuses.

DR. GENCO: Any others?

DR. MORGAN: Would you consider mandibular fractures in severely atrophic mandibles that were trying to be restored with root forms?

DR. HEFFEZ: I would agree.

DR. GENCO: Now we get into--some of these are

probably related to any or all surgery you do. I mean, you could break a person's jaw. You could have an air embolism not related to implants particularly. Are there any others, then?

[No response.]

DR. GENCO: Okay. The recommended panel classification is class II. What is the priority? Now, what does that mean, the priority for FDA making this final decision?

MS. SCOTT: Yes. That's the--

DR. GENCO: Okay. What is the panel's feeling about the priority? What are the options here? What does high priority mean, something within weeks, months? I know this has been going on for a couple of months, anyway.

MR. ULATOWSKI: It's been going on for years. In the general scheme of things, considering current, it would probably be within this year, fiscal year.

DR. GENCO: So not high but moderate?

MR. ULATOWSKI: High would be this fiscal year.

[Laughter.]

DR. GENCO: Well, I'm glad to hear that, because I was on the panel in 1991.

Okay. If the device is an implant or is life-sustaining or life-supporting and has been classified

in a category other than the class III, explain fully reasons for the lower classification with supporting documentation. I think we'll defer on that because that's really what we've been doing for about four days. These forms are really brutal, but bear with me.

Summary of information, including clinical experience or judgment upon which a classification is based. We can do that later.

Identification of any needed restrictions on the use of the device. I think we should do that now, restrictions on the use of the device. In non-growing--

DR. REKOW: Didn't se just do that?

DR. GENCO: Well, yes, but bear with these forms. One day, you and I will sit down and we'll redo the forms for the FDA.

DR. REKOW: No.

[Laughter.]

DR. GENCO: Restrictions on the use of the device. In non-growing--I mean, in growing adults, in growing individuals.

MR. ULATOWSKI: It depends how you want to consider that. That sort of thing, you can look at two different ways. One way is in labeling people, may say, depending on the data, there's no data that show the safety

and effectiveness in this group of patients so you have to be cautious. The other way is, we found out that if you do it, these are the problems.

DR. GENCO: I think that's the case.

MR. ULATOWSKI: So you're not limiting a dental professional from moving forward based on his or her experience and knowledge necessarily. You're informing, but allowing, as well. By restricting, you're saying, no.

DR. HEFFEZ: So is that a contraindication versus a precaution?

MR. ULATOWSKI: Yes.

DR. HEFFEZ: So our label is for precautions and not contraindications?

DR. GENCO: Okay. Precautions--

MR. ULATOWSKI: Unless that's your decision.

DR. GENCO: No. I think, obviously, there are uses in growing individuals that the NIDR has worked out very nicely, in ectodermal hyperplasia, or dysplasia. But I think the precaution--how does that sound--precautions in growing individuals, precautionary use in growing individuals.

Any other? I mean, there are obvious surgical and risk factor precautions. Do we get into that or is that something that's well known, shouldn't be used in

uncontrolled diabetics--

MR. ULATOWSKI: Well, those are things we probably--well, you can recommend those things, although we would pick those up in the normal course of business.

DR. GENCO: All right. And they're not all that well studied anyway. I think we'd be a little uncomfortable with that.

I think we're finished with this form.

MR. ULATOWSKI: On the data, what basis of data--

MS. SCOTT: Right, number eight.

MR. ULATOWSKI: All you need to say is--I suggest that all you need to say is, based on the presentations and data submitted by the applicants and other speakers and the basis of our own experience utilizing these products and so on and so forth.

DR. GENCO: All right. Now, we've got another question to deal with. The Dental Products Panel recommended that abutments be classified separately from the implant fixture. What is your feeling, panel? Should the abutments be classified separately from the implant fixture, and if so, what classification? Does anybody want to start the discussion?

DR. HEFFEZ: Leslie Heffez. I feel that this should be classified differently and it should be classified

as class II.

DR. GENCO: Okay. Process, now. Pam, do we go through the same process for the abutments?

MS. SCOTT: Yes.

DR. GENCO: Okay.

MS. SCOTT: If you're recommending classification into a different class, then we would need you to fill out the questionnaire, take the vote, and the supplemental data sheet.

DR. GENCO: Yes?

MR. LARSON: Point of clarification. We're talking about abutments, using the term abutments. In the ISO task group, we recognized that we had a real terminology problem when we were talking about testing things and I'm not sure what to suggest, but the word "abutment" is a real difficult thing to explain in a generic sense. So I wonder if we can come up with a more generic term?

DR. GENCO: I think that we heard the definition of an abutment was everything but the implant--

MR. LARSON: Yes.

DR. GENCO: --and the implant has within it a place for the screw. So it's everything but the root portion of the implant.

MR. LARSON: Okay. Rather than using the term

"abutment", could we use the term prosthetic components?

DR. GENCO: Okay. All prosthetic components normally used with implants? Maybe we could have a suggestion for the term here. Yes, please, Dr. Marlin?

DR. MARLIN: If you go into all prosthetic components, then you're getting into crowns and over-denture prosthesis and I think that that would be kind of like awfully hard to regulate. If I might suggest that all prosthetic components that are directly connected to the implant would serve as the abutment.

MR. LARSON: And maybe manufactured could be in there, too?

DR. MARLIN: Yes. Let's rephrase that. All manufactured prosthetic components that are directly connected to the implant would serve as the abutment, or that serves as--to receive another prosthesis of some form. In other words--

MR. LARSON: Okay, but could we use the terminology, actually, manufactured prosthetic components? We don't want to get into the temporary things that could be class I or--

DR. MARLIN: Right.

DR. GENCO: Premanufactured means not fabricated by the dentist.

DR. MARLIN: Right.

DR. GENCO: Is that what you mean?

DR. MARLIN: But you could have, for instance, as an example, a castable pattern that's premanufactured. A premanufactured directly connected component or to be used as a castable piece that's been--in other words, using the word "premanufactured", I think, pretty much covers it, that's directly connected to the--

DR. GENCO: So those are the two essential components, premanufactured, directly coupled.

DR. MARLIN: Correct.

DR. GENCO: Thank you.

MR. LARSON: But what will be the actual words that are used as the title? Are you still thinking abutment?

DR. MARLIN: I think in the clinician's side, they look at an abutment as that. But if you determine that it has premanufactured or premachined, using the terminology we just did, you can use the term abutment because you've defined it more narrowly. Is that helpful?

MR. LARSON: Okay. It's just we found in Bangkok as we were talking about this that we had no idea when we finished what we really meant by abutment.

DR. MARLIN: Yes.

DR. GENCO: What if we say something like this, implant abutments. I mean, that's the common term.

DR. MARLIN: Right. Shall be defined as--

DR. GENCO: Yes, to include--

DR. MARLIN: To include.

DR. GENCO: --all premanufactured prosthetic components directly connected to implants.

DR. MARLIN: Right.

DR. GENCO: Okay. Are these life-sustaining or life-supporting? No.

Is the device for a use which is of substantial importance in human health? Yes.

Is there potential unreasonable risk of illness or injury? No.

Number four, did you answer yes to any of the above three questions? Yes.

Number five--

MS. SCOTT: Then you to go seven.

MR. ULATOWSKI: Then go to seven.

DR. GENCO: Seven, is there sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness? I heard yes. That means that they should be in class II and so if that's the case, it looks like we are probably ready for a motion.

DR. HEFFEZ: I move that the so-called abutments be classified as class II devices.

DR. GENCO: Does anyone second that?

DR. MORGAN: I second the motion.

DR. GENCO: Seconded, Andrea. Any discussion? Anybody uncomfortable with that?

[No response.]

DR. GENCO: Okay. Are we ready for the vote? Any discussion? Any comments?

[No response.]

DR. GENCO: Let's start at the top of the list here. Janine?

DR. JANOSKY: I agree.

DR. GENCO: Willie?

DR. STEPHENS: I agree.

DR. GENCO: Mark?

DR. PATTERS: Agree.

DR. GENCO: Dr. Brunski?

DR. BRUNSKI: Agree.

DR. GENCO: Dr. Heffez?

DR. HEFFEZ: Agree.

DR. GENCO: Dr. Morgan?

DR. MORGAN: Agree.

DR. GENCO: Dr. Rekow?

DR. REKOW: Agree.

DR. GENCO: Thank you. Now, what are the special controls? Do we have voluntary performance standards here, Floyd?

MR. LARSON: Yes.

DR. GENCO: Are we satisfied with those? Do we want to make any comment to them?

MR. LARSON: I think the combination of voluntary standards and testing guidelines would provide very good control of these.

DR. GENCO: And those are fairly well in hand, fairly well established, or are in the process of being established by reputable groups?

[Laughter.]

MR. LARSON: Reputable or not. No, really, they're the same ones that we were talking about before.

DR. GENCO: Okay. Does anybody want to make any further recommendations for special controls?

[No response.]

DR. GENCO: Are we comfortable, then with class II with special controls? The special controls are well in hand in terms of performance and testing standards.

[No response.]

DR. GENCO: There's no regulatory performance

standard needed for this, is that true? So question two is not applicable, also. Also, question three is not applicable.

Is there anything that we should be concerned about the restricted sale, distribution, or use because of any potential harmful effect? No? It's prescription use. So that's yes, then.

Supplemental data, generic device, we'll reword that, advisory panel. Is the device an implant? No.

Indications for prescribed use, recommended use--do you have some words, Floyd, for the indications for use?

MR. LARSON: I'm sorry.

DR. GENCO: Well, if you do, we can put that in, indications for use of these abutments. Is this to replace--

MR. LARSON: Well, there's nothing in the regs right now, so we have to come up with it.

DR. GENCO: Okay. Does somebody want to make some suggestions? These abutments are, what, to--

DR. RUNNER: How about as an aid for prosthetic rehabilitation?

DR. GENCO: That sounds good. Okay.

Any risk to general health? Any risk

specifically, specific hazards with their use? No?

DR. REKOW: Well, I don't think we can be quite that--

DR. GENCO: Okay.

DR. REKOW: There's a potential, again, it's related to clinician practice, but you could potentially have parts that get dropped. I mean, there's all those little nonsense things. If you have a second surgery, you've got all this stuff that's related to the second surgery to uncover them and all those related things.

DR. GENCO: You mean the surgical complications associated with second surgery?

DR. REKOW: Yes. I mean, it's certainly a lot easier surgery than the first one, but there's still an open wound that you're creating to do the transcutaneous portion of it.

DR. GENCO: Okay. Any other specific hazards?

MS. SCOTT: Originally, the panel identified also, and the panel may want to discuss this, as to whether or not this is still appropriate, abutment fractures, screw fractures.

DR. REKOW: Excuse me, Pam. What did you say?

MS. SCOTT: Originally, I believe, if I'm not wrong, the classification panel originally identified

abutment fractures as one of the risks.

DR. GENCO: And screw fractures. Any others?

DR. HEFFEZ: If it does fracture, it could also lead to loss of the implant. I don't know if that has to be mentioned. It could render the implant not useful.

DR. GENCO: Okay. Any others?

[No response.]

DR. GENCO: All right. We're recommended class II. The priority here, high again, since this has been under discussion for a long time. Is that the panel's recommendation, high priority?

[No response.]

DR. GENCO: Okay.

DR. HEFFEZ: Can I go back to hazards of health? Also, I would think if the fracture of the abutment goes unnoticed and it's a two-unit component, it could affect the health of the adjacent dentition or adjacent implants.

DR. GENCO: Okay. Now, if the device is an implant or is life-sustaining or life-supporting, has been classified in a category other than class III, what are our reasons for the lower classification? Is this that generic statement, the reasons that we've heard?

DR. HEFFEZ: It's not an implant, though.

DR. GENCO: Oh, it's not an implant, so that's not

applicable.

So the summary of information is based upon what has been presented to the FDA. Okay.

Any needed restrictions on the use of the device other than the prescription?

[No response.]

DR. GENCO: Okay. Are there existing standards applicable to the device? There are, these testing standards and these materials standards.

MR. LARSON: Certainly the materials standards.

DR. BRUNSKI: Perhaps we should just say, see the relevant sections of the guidance document.

DR. GENCO: Okay. I think we've answered those three questions. Is there anything else that you want us to deal with?

DR. RUNNER: You haven't made a recommendation on the blade implants.

DR. GENCO: Okay. So we collapsed everything except the blade implants. What is your feeling?

DR. HEFFEZ: Also, the Onplant. We did not discuss that.

DR. GENCO: We did not discuss the Onplant. What are your feelings with respect to the blade implant? One possibility is to leave it in class III. Another

possibility is to reclassify it class II. Does anybody want to start the discussion? Dr. McCarthy, you've been quiet.

DR. McCARTHY: I'd like to stay that way.

[Laughter.]

DR. GENCO: I didn't mean to put you on the spot.

DR. McCARTHY: I think the blade is really--I have no clinical experience whatsoever with the blade implant. To me, it's a unique piece of equipment. I think it is--while it resides in the bone, in that respect, it's endosseous, I think the study that got quoted to this panel, it's not good to have an institutional memory, but in '91, it was the Kapur study and the Kapur studies really have raised more question about it than they answered, I think. So, I mean, I would favor leaving it as a class III device.

DR. GENCO: Now, since then, there are some monkey studies, the Fritz studies. Is anybody aware of any other human studies that would make us think any differently? Yes?

DR. SCHNEIDER: Yes. In Europe, there are--

DR. GENCO: Do you want to identify yourself and come to the microphone?

DR. SCHNEIDER: I'm Dr. Raymond Schneider. In Europe, the blade implant is more highly received. I want to first point out that one of our pre-amendment device, a

Ramus implant, was started. Just a little history on blade implants. They are extremely effective. It depends where. It's also site-specific.

For example, I'll give you the Ramus implant is a one-stage site-specific implant in the posterior. It is made by Pacific Implant Company and they only really basically make that one implant, Ralph Roberts. When that was a pre-amended device, and I have several of that type in patients and of all of them that I've done, only one has been removed by mistake. So anything I've had is just the prejudice of other practitioners thinking that they're poor implants.

If a blade can be put on good solid bone, it is going to be just as effective as any other implant. So what I'm saying is those studies, yes, in Europe there are some very fine, excellent studies that show its usage. But again, it's site-specific. When it's used in the proper indication, they have very good statistics on those implants.

DR. GENCO: I don't think we have been presented with them. In contrast to the other data, and I was on the panel in '91, I mean, there's been a tremendous amount of data presented since '91 on the others and I'm just--

DR. SCHNEIDER: I would ask the panel to ask for

data and I'm sure that it can be brought forward, some very fine testimony. I didn't hear that today, but I didn't hear anybody asking for that data.

DR. GENCO: We had a presentation at the last meeting in November which was really the core data. Again, as I recall, no new data to my mind, except for the Fritz studies in the monkey where they're taking a very different approach.

DR. SCHNEIDER: What I found was the problem is a lot of the practitioners weren't bringing data forward because of hearing that it was a pre-amendment device, that no longer--they were grandfathered in, and grandfathered in to them means forever. They don't have to bring information forward. I know that's not true, but I'm saying for the professionals. Now, that is not true in Europe. In Europe, they really have to continue on their studies and they had that. So I think in the United States, maybe some of those studies have not been backed up, but they are available and I would not like to see for the American public all those blades put into a class III.

DR. GENCO: I think ample opportunity was there for those studies to come in. Susan?

DR. RUNNER: They already are class III. It's a matter of whether you want to reclassify them as class II.

DR. GENCO: Right.

DR. SCHNEIDER: So in other words, my understanding is implants that are already approved will not be disapproved just from this statement.

DR. RUNNER: No, but if they remain in class III, then PMAs would be called for for blade implants.

DR. McCARTHY: What I think it amounts to is that we've not seen any data from the manufacturer or manufacturers. At least, I haven't seen anything compelling or convincing to make me want to think that these should be class II. They may very well be. Like I said, I don't have any clinical experience whatsoever.

DR. GENCO: I think the panel was quite open to data and reclassifying a whole series of endosseous implants, quite different from what we heard in '91. But we haven't heard that same data for the blade implants, and I think if we had and it was reasonable--

DR. SCHNEIDER: As a member of the American Academy of Implant Dentistry and International Congress of Implant Dentistry, in as far as being represented in the world community and seeing what's going on, I was over in Germany in the DGZI. I'm really surprised that you do not have that information. I find that--I'm very concerned for the public.

DR. GENCO: You heard it today. We got a lot of data from Europe today on other implants, so I don't understand, either, if it's there. At any rate, thank you very much for bringing this up.

I ask the panel, then, is there reason to reclassify blade implants into class II or do something else with them or leave them in class III for the time being? Yes?

DR. HEFFEZ: My suggestion is we don't have enough data to change the classification. We can table it and leave it as a class III.

DR. GENCO: What is the process? Is the process to leave it, to ask for more data, to ignore it? How do we go about it? Do we have to make a positive decision?

MR. ULATOWSKI: Well, the--

DR. GENCO: Or recommendation?

MR. ULATOWSKI: Come the time to submit a PMA, the applicant can always petition for reclassification, even now, but I'm not sure we'd bring it back until we saw some effort there.

DR. GENCO: Okay. Fine. So the feeling of the panel is to not reclassify it, to leave it as is, is that right? Does somebody want to make that as a motion? Floyd?

MR. LARSON: I can't move, but--

DR. GENCO: No. Do you have something to say?

MR. LARSON: I did have a question. Procedurally, then, do the regs get written with blade implants described using the existing class III endosseous implant definition and with root form removed from that definition?

MR. ULATOWSKI: Yes. We'd have to modify that.

MR. LARSON: Okay. But you do that. We don't have to do that.

DR. STEPHENS: Is this blade implants only or are we including Ramus implants in that group of implants with these?

DR. GENCO: I think we had some data on blade implants, the Kapur study, but nothing on Ramus or others that I was aware of, either '91 or November or now.

DR. RUNNER: I believe the subperiosteals are a different classification, correct, the subperiosteals?

MR. LARSON: The subperiosteals are custom.

DR. RUNNER: They're in a different class.

DR. GENCO: And the Ramus ream is not custom. That's premanufactured, so that could conceivably be placed in the same category as blade, is that what you're saying?

DR. STEPHENS: That's what the question is.

DR. GENCO: The question is. Has anyone--

DR. BRUNSKI: I know I did, in the packet of all

the stuff we've received, I know I have seen something about the Ramus ream from Dr. Roberts. I know it's in our packet. Now, whether that implies that it was--I mean, I have seen something in our packet.

DR. GENCO: Is there enough data to deal with that, either as a part of the blade definition or separate?

DR. HEFFEZ: I think if we were to define blade implant, then generically, I would think the Ramus ream would fall into that category since it is essentially a slot made in the bone and an implant banged into it.

DR. STEPHENS: Then I would make the motion that we leave the Ramus ream and the blade implants in class III for the time being.

DR. GENCO: Second to that?

DR. REKOW: I'll second it.

DR. HEFFEZ: I second it.

DR. GENCO: Okay. Further discussion? Comments?

[No response.]

DR. GENCO: Let's take the vote, then. Diane?

DR. REKOW: I approve of the--yes.

DR. GENCO: Dr. Morgan?

DR. MORGAN: I agree.

DR. GENCO: Dr. Heffez?

DR. HEFFEZ: Agree.

DR. GENCO: Dr. Brunski?

DR. BRUNSKI: I agree.

DR. GENCO: Dr. Stephens?

DR. STEPHENS: I agree.

DR. GENCO: Dr. Janosky?

DR. JANOSKY: I agree.

DR. GENCO: Okay. Thank you.

Now, the Onplant. Is there an action to be taken or is their 510K approved or what's the status and what can we do to help?

MR. ULATOWSKI: Let us talk for just a moment here.

DR. GENCO: Surely.

[Pause.]

MR. ULATOWSKI: Our recommendation would be to not consider it at this time as within the bins that have been discussed today.

DR. GENCO: Okay. Fine. Thank you. So it's neither endosseous, it's neither blade endosseous or any of the other categories.

MR. ULATOWSKI: Its status is pending.

DR. GENCO: Okay. Fine. Thank you very much.

MR. LARSON: Mr. Chairman?

DR. GENCO: Before we leave the class III, we have

to give Pam or the FDA our reasons for leaving blades and Ramus in class III. Can I paraphrase some of that discussion as that we didn't see any data that would justify putting either one of those into class II, in contrast to some of the other implant data, the root forms, which there was a remarkable amount of information obtained between '91 and present which would justify reclassification. Any other comments as to the reason for leaving those two in class III?

[No response.]

DR. GENCO: Okay. Any further comments?

MR. LARSON: I just had a question about other indications within the root form area. How far are we extending the root form area in terms of, for example, it was mentioned briefly that there are orthodontic indications for a root form type of implant in addition to the Onplant. Is that covered here, or how are we handling that?

DR. GENCO: Good question. What is your feeling?

DR. RUNNER: The way we've dealt with those indications is that we've found them substantially equivalent to endosseous implants for other indications because they're placed--

MR. LARSON: On the basis of clinical data?

DR. RUNNER: Yes.

DR. GENCO: Anything else that you'd like us to discuss, Susan, Tim, Pam?

[No response.]

DR. GENCO: Okay. Fine. I'd like to thank the panel for this marathon session and I'd like to thank those from industry. It was a very productive session. And thank you, staff, for treating us so well. We will see you in the summer.

[Whereupon, at 4:47 p.m., the meeting was adjourned.]

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